

Microbot Medical Inc.  
Form 8-K  
January 04, 2017

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**  
**PURSUANT TO SECTION 13 OR 15(d)**  
**OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of report (Date of earliest event reported): January 4, 2017**

**MICROBOT MEDICAL INC.**  
**(Exact Name of Registrant as Specified in Charter)**

**Delaware**  
**(State or Other Jurisdiction**  
**of Incorporation)**

**000-19871**  
**(Commission**  
**File Number)**  
**175 Derby Street, 27/1**

**94-3078125**  
**(I.R.S. Employer**  
**Identification No.)**

Edgar Filing: Microbot Medical Inc. - Form 8-K

**Hingham, MA 02043**

**(Address of Principal Executive Offices) (Zip Code)**

**Registrant's telephone number, including area code: (908) 938-5561**

**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

---

## GENERAL NOTE

On November 28, 2016, C&RD Israel Ltd. ( Merger Sub ), a wholly-owned subsidiary of Microbot Medical Inc. (then known as StemCells, Inc.; the Company ), completed its merger with and into Microbot Medical Ltd. ( Microbot Israel ), with Microbot Israel surviving as a wholly-owned subsidiary of the Company (the Merger ). On November 28, 2016, in connection with the Merger, the Company changed its name from StemCells, Inc. to Microbot Medical Inc. This Current Report on Form 8-K is being filed by the Company to update and describe certain material changes to the business of the Company following and as a result of the Merger.

The financial information, including the operating and financial results and audited financial statements included in this Current Report on Form 8-K are that of Microbot Israel rather than that of our Company prior to the completion of the Merger.

## FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements. Forward-looking statements are projections in respect of future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as may , should , intends , expects , plans , anticipates , believes , estimates , predicts , continue or the negative of these terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks listed under the section entitled Risk Factors commencing on page 20 of this report, which may cause our or our industry s actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity or performance. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

In this Current Report, unless otherwise specified, all dollar amounts are expressed in United States dollars. Except as otherwise indicated by the context, references in this report to Company , Microbot , we, us and our are reference Microbot Medical Inc., formerly known as StemCells, Inc., including the operating and financial results of Microbot Israel. References to Microbot Israel refer to such company prior to the Merger.

### Item 8.01 Other Events

#### DESCRIPTION OF BUSINESS

##### The Company

Our Company was incorporated on August 2, 1988 in the State of Delaware under the name Cellular Transplants, Inc. The original Certificate of Incorporation was restated on February 14, 1992 to change the name of the Company to Cytotherapeutics, Inc. On May 24, 2000, the Certificate of Incorporation as restated was further amended to change the name of the Company to StemCells, Inc. As of the Merger, on November 28, 2016, the Company changed its name from StemCells, Inc. to Microbot Medical Inc. Pursuant to the terms of the Merger, at the effective time of the Merger, each outstanding share of Microbot Israel capital stock was converted into the right to receive approximately 2.90 shares of our common stock, par value \$0.01 per share (the Common Stock ), after giving effect to a one for nine reverse stock split, for an aggregate of 26,644,979 shares of Common Stock issued to former Microbot



Israel shareholders. In addition, all outstanding options to purchase the ordinary shares of Microbot Israel were assumed by the Company and converted into options to purchase shares of the Common Stock. On November 29, 2016, the stock of the Company began trading on the Nasdaq Capital Market under the symbol **MBOT**.

Prior to the Merger, the Company was a biopharmaceutical company that operated in one segment, the research, development, and commercialization of stem cell therapeutics and related technologies. Following the Merger, the Company is now a pre-clinical medical device company specializing in the research, design and development of next generation micro-robotics assisted medical technologies targeting the minimally invasive surgery space. The Company is primarily focused on leveraging its micro-robotic technologies with the goal of improving surgical outcomes for patients.

Microbot is currently developing its first two product candidates: the Self Cleaning Shunt, or SCS, for the treatment of hydrocephalus and Normal Pressure Hydrocephalus, or NPH; and TipCAT, a self-propelling, semi-disposable endoscope that is being developed initially for use in colonoscopy procedures. Microbot's product candidates are being designed to bring greater functionality to conventional medical devices and to reduce the known risks associated with such devices. Microbot is currently aiming to complete pre-clinical or clinical data collection for both product candidates within the next 24 months and is targeting approval or clearance for SCS by late 2018.

Microbot currently holds an intellectual property portfolio that comprises nine patent families, which include eight patents granted in the United States, eleven patents granted outside the United States, and 17 patent applications pending worldwide, with other patent applications under development, as well as an exclusive license to key components of its technology.

## **Industry Overview**

### *Shunt Systems*

Hydrocephalus is a medical condition in which there is an abnormal accumulation of cerebrospinal fluid, or CSF, in the brain that can cause increased intracranial pressure. It is estimated that one in every 500 babies are born with hydrocephalus, and over 1,000,000 people in the United States currently live with hydrocephalus.

Symptoms of hydrocephalus vary with age, disease progression and individual tolerance to the condition, but they can include convulsion, tunnel vision, mental disability or dementia-like symptoms and even death. Normal Pressure Hydrocephalus ( NPH ) is a type of hydrocephalus that usually occurs in older adults. NPH is generally treated as distinct from other types of hydrocephalus because it develops slowly over time. In NPH, the drainage of CSF is blocked gradually and the excess fluid builds up slowly. This slow accumulation means that the fluid pressure may not be as high as in other types of hydrocephalus. It is estimated that more than 700,000 Americans have NPH, but less than 20% receive an appropriate diagnosis.

Hydrocephalus is most often treated by the surgical insertion of a shunt system. The shunt system diverts the flow of CSF from the brain's ventricles (or the lumbar subarachnoid space) to another part of the body where the fluid can be more readily absorbed. Hydrocephalus shunt designs have changed little since their introduction in the 1950s. A shunt system typically consists of three parts: the distal tubing or shunt (a flexible and sturdy plastic tube), the ventricular catheter (the proximal catheter), and a valve. The end of the shunt system with the proximal catheter is placed in the ventricles (within the CSF) and the distal catheter is placed in the site of the body where the CSF can be drained. A valve is located along the shunt to maintain and regulate the rate of CSF flow. Current systems can be created from separate components or bought as complete units.



The treatment of hydrocephalus with existing shunt systems often includes complications as well. For example, approximately 50% of shunts used in the pediatric population fail within two years of placement and repeated neurosurgical operations are often required. Ventricular catheter blockage, or occlusions, is by far the most frequent event that results in shunt failure. Shunt occlusion occurs when there is a partial or complete blockage of the shunt that causes it to function intermittently or not at all. Such a shunt blockage can be caused by the accumulation of blood cells, tissue, or bacteria in any part of the shunt system. In the event of shunt occlusion, CSF begins to accumulate in the brain or lumbar region again and the symptoms of untreated hydrocephalus can reappear until a shunt replacement surgery is performed.

Although several companies are active in the field of hydrocephalus treatment and the manufacturing of shunt systems and shunt components, Microbot believes that the majority of those companies are focusing on the development of valves. The development of a smart shunt—a shunt that could provide for weaning from shunt dependency or increase personalized control through advanced control algorithms, that could provide data to the physician on patient conditions and shunt function with sensor based controls, or correct the high failure rate of existing shunt systems—is for the most part at an academic and conceptual level only. Reports of smart shunt technologies are typically focused on a subset of components with remaining factors left unspecified, such as hardware, control algorithms or power management. Microbot does not believe that a smart shunt has been developed to date. Because of the limited innovation in this area, Microbot believes an opportunity exists to provide patients suffering from hydrocephalus or NPH with a more effective instrument for treating their condition.

#### *Endoscopic Equipment*

Endoscopes are medical devices used to look inside a body cavity or organ with minimally invasive surgery. The North American flexible endoscopes market was valued at \$1.27 billion in 2013, and is expected to reach \$1.91 billion by 2018, at a CAGR of 8.5% during the period 2013 to 2018.

Colonoscopy is a procedure that allows a physician to examine the colon using an endoscope. It is a commonly performed procedure for the diagnosis and treatment of a range of conditions, including for the screening and surveillance of colorectal neoplasia, or colorectal cancer. Annually, between 15 and 20 million endoscopy procedures are conducted in the United States with reusable endoscope devices to screen various sections of a patient's gastrointestinal, or GI, tract. However, according to data from the American Cancer Society, it is estimated that over 49,000 Americans will die from colorectal cancer and 95,000 new cases of colon cancer will be diagnosed in 2016. It is the third leading cause of cancer deaths in spite of being highly preventable with early identification and removal of colorectal adenomas, or polyps. Colonoscopy with removal of colorectal polyps has been shown to be the most effective way of preventing colorectal cancer. And colonoscopy is generally considered the gold standard for the detection and treatment of adenomas. However, using current colonoscopic technology, approximately 30% of polyps are missed. In addition, the technique remains underutilized—less than 50% of eligible Americans, based on guidelines established by organizations including the American Cancer Society, United States Preventive Services Task Force, and U.S. Multi-Society Task Force on Colorectal Cancer, have undergone screening, with more than 45% of colon cancers being diagnosed at a time when the cancer has become incurable. This reluctance can be linked to patients' general discomfort associated with the colonoscopy screening procedure, due to the use of mechanical force to insert the endoscope into the colon. The procedure is widely perceived to be uncomfortable, and it also can sometimes damage or perforate the bowel wall.

Colonoscopy techniques that improve the Adenoma Detection Rate, or ADR, and reduce patient discomfort could optimize the potential of colonoscopy for the prevention of colorectal cancer. Microbot believes that it has the potential to develop a robotic endoscope product that addresses this issue of patient





discomfort, which it believes will improve patients' willingness to get this important screening test with the additional benefit of providing a new tool to health care practitioners for use in the identification and treatment of colorectal polyps.

## **Microbot's Product Pipeline**

### *Self-Cleaning Shunt (SCS)*

The Self-Cleaning Shunt, or SCS, device is designed to act as the ventricular catheter portion of a CSF shunt system that is used to relieve hydrocephalus and NPH. It is designed to work as an alternative to any ventricular catheter options currently on the market and to connect to all existing shunt system valves currently on the market; therefore, the successful commercialization of the SCS is not dependent on any single shunt system. Initially, Microbot expects the SCS device to be an aftermarket purchase that would be deployed to modify existing products by the end user. Microbot believes that the use of its SCS device will reduce, and potentially eliminate, shunt occlusions, and by doing so Microbot believes its SCS has the potential to become the gold-standard ventricular shunt in the treatment of Hydrocephalus and NPH.

The SCS device embeds an internal robotic cleaning mechanism in the lumen, or inside space, of the ventricular catheter which prevents cell accumulation and tissue ingrowth into the catheter. The SCS device consists of a silicone tube with a perforated titanium tip, which connects to a standard shunt valve at its distal end. The internal cleaning mechanism is embedded in the lumen of the titanium tip. Once activated, the cleaning mechanism keeps tissue from entering the catheter perforations while maintaining the CSF flow in the ventricular catheter.

The internal cleaning mechanism of the SCS device is activated by means of an induced magnetic field, which is currently designed to be externally generated by the patient through a user-friendly headset that transmits the magnetic field at a pre-determined frequency and operating sequence protocol. The magnetic field that is created by the headset is then captured by a flexible coil and circuit board that is placed just under the patient's scalp in the location where the valve is located. The circuit board assembly converts the magnetic field into the power necessary to activate the cleaning mechanism within the proximal part of the ventricular catheter.

Microbot has completed the development of an SCS prototype and is currently completing the safety testing, general proof of concept testing and performance testing for the device, which Microbot began in mid-2013. Microbot had a pre-submission meeting with the FDA in early 2014, and has been working closely with Washington University in St. Louis to develop the protocol for and to execute the necessary animal study. Microbot expects the animal study to start in the first quarter of 2017. Upon the completion of animal studies, Microbot may conduct clinical trials if they are requested by the FDA or if Microbot decides that the data from such trials would improve the marketability of the product candidate. Microbot believes that the first generation of its SCS device should receive regulatory approval or clearance from FDA by late 2018. The proposed indication for use of the SCS device would be for the treatment of hydrocephalus as a component of a shunt system when draining or shunting of CSF is indicated.

Microbot may also conduct clinical trials for the SCS in other countries where such trials are necessary for Microbot to sell its SCS device in such country's market, although it has no current plans to do so.

### *TipCAT*

The TipCAT is a semi-disposable, flexible, self-propelled endoscope. A mechanism comprising a series of interconnected balloons at the device's tip provides the TipCAT with its forward locomotion capability. The device has the capability to self-propel within natural tubular lumens such as the colon, blood vessels, and the urinary tract. The TipCAT is designed to be fully-equipped with a contemporary endoscope, including a high-quality camera, steering capability and a standard working channel for treatments. The TipCAT thus offers functionality and visualization features equivalent to modern endoscopes, along with unique advantages associated with its physiologically adapted self-propelling mechanism, flexibility, and design.

The TipCAT consists of two parts:

A disposable self-propulsion module, which is a series of interconnected, sequentially inflatable balloons constructed on an inner tube (i.e., the working channel); and

A re-usable module isolated from contact with the tissue/body fluids, containing a camera, LED lighting and a steering system.

In the self-propulsion module, the air to inflate the balloons is supplied from a single channel. The sequential inflating and deflating of the balloons creates an inchworm-like forward motion. Therefore, unlike standard endoscopes, the TipCAT does not need to be mechanically forced into the patient's lumen using external pressure; rather, it will gently advance itself through the organ's anatomy. As a result, the TipCAT is designed to be able to reach every part of the lumen under examination regardless of the topography, be less operator dependent, and greatly reduce the likelihood of damage to lumen structure.

Furthermore, Microbot believes that use of the TipCAT will improve ADR by straightening the intestinal topography, smoothing colon topography and improving tissue visualization. In addition, by incorporating the TipCAT in therapeutic procedures, Microbot believes that the inflated balloons will provide the additional benefits of assisting the physician in centralizing endoscope optics and allowing for the colonoscope to be secured in each treatment position throughout the procedure, resulting in more efficient and effective procedures.

The TipCAT is also designed such that only disposable parts are in direct contact with the lumen tissue, which should eliminate the risk of cross contamination between patients and the need for post-use reprocessing. Reducing dependence on reprocessing procedures is important from a regulatory perspective because safety issues related to the reprocessing of reusable medical devices are a growing concern for regulatory authorities.

A TipCAT prototype was shown to self-propel and self-navigate in curved plastic pipes and curved ex-vivo colon. In addition, in its first feasibility study, the prototype device was tested in a live animal experiment and successfully self-propelled through segments of the animal's colon, with no post-procedural damage. All tests were conducted at AMIT (Alfred Mann Institute of Technology at the Technion), prior to the licensing of TipCAT by Microbot. Microbot is currently reviewing the design and general proof of concept of the TipCAT and working closely with experts in the field to define the optimal design. Microbot expects animal studies for this device to begin in 2017. Upon the completion of animal studies, Microbot may conduct clinical trials if they are requested by the FDA or if Microbot decides that the data from such trials would improve the marketability of the product candidate. Regulatory approval or clearance for marketing the TipCAT colonoscope in the United States is targeted to occur soon after the applicable animal or clinical trials are completed, depending on when the applicable premarket submission is finalized and filed with FDA, and Microbot's ability to raise money and conduct the necessary trials for approval.



Microbot also plans to further develop the TipCAT for application for other diagnostic and therapeutic endoscopic procedures outside of colonoscopy, such as Chronic Total Occlusion, or CTO, urethroscopy and catheterization.

Microbot may conduct clinical trials for the TipCAT in other countries where such trials are necessary for Microbot to sell its TipCAT device in such country's market, although it has no current plans to do so.

## Strategy

Microbot's goal is to generate sales of its products, once they have received regulatory approval, by establishing SCS and TipCAT devices as the standard-of-care in the eyes of doctors, surgeons, patients and medical facilities, as well as getting the support of payors and insurance companies. Microbot believes that it can achieve this objective by working with hospitals to demonstrate the key benefits of its products. Microbot's strategy includes the following key elements:

**Continue to refine existing product candidates and develop additional micro-robotic solutions.** As Microbot prepares to bring its initial product candidates through pre-clinical and clinical trials, if necessary, and eventually to market, it continues to focus on improving its product candidates to respond to clinical data and patient and physician feedback. Microbot also expects to continue to innovate in the micro-robotics field by continuing to find ways of using its technology to solve unmet needs, with the overarching goal of providing a safer, more effective and more efficient surgical environment for patients and physicians.

**Establish and leverage relationships with key institutions and leading clinicians.** Microbot intends to develop relationships with a relatively small number of hospitals and clinics through its clinical stage. Microbot's objective will be to maintain clinical focus with such hospitals and clinics so as to establish the SCS and TipCAT as the standard of care in such institutions for their respective procedures. Microbot also expects to identify key clinicians in the hydrocephalus and colonoscopy specialties with the expectation that such clinical focus will accelerate the adoption of its candidate products.

**Invest in research and development.** Microbot's most significant expense has historically been research and development, and Microbot expects that this will continue in the foreseeable future, including expenses it expects to incur to improve on its prototype products in order to respond to clinical data, to develop additional applications using its technologies and to develop future product candidates.

**Explore partnerships for the introduction of Microbot's products.** Microbot intends to focus its marketing and sales efforts initially on pursuing collaborations with global medical device companies that have established sales and distribution networks. Microbot will seek to enter collaborations and partnerships with strategic players that offer synergies with Microbot's product candidates and expertise.

**Seek additional IP and technologies to complement and strengthen Microbot's current IP portfolio.** Microbot intends to continue exploring new technologies, IP and know-how to add to its current portfolio and to allow Microbot to enter new spaces and strengthen its overall product portfolio.

### *SCS Opportunities*

The SCS is designed to prevent shunt occlusions in hydrocephalus and NPH patients who have undergone or are undergoing the surgical insertion of a shunt system. For purposes of its marketing strategy, Microbot has split the market for shunt systems into two sub-markets:

Primary shunt placement; and

Shunt replacement.

Microbot's SCS device is universal (meaning that it is designed to be attachable to any valve on the market); therefore, Microbot's initial go-to-market strategy is the development of strategic partnerships with leading global medical device companies with ready sales and distribution channels. Outside of a strategic partnership, it is most likely that Microbot's SCS product will be initially used in shunt replacement surgeries to replace occluded ventricular catheters. Accordingly, Microbot intends to establish key hospital and clinic relationships that will allow it to diffuse the technology among experts and other stakeholders. Microbot is also planning to apply for the SCS device to be covered under the current reimbursement codes in the United States for use in hydrocephalus and NPH shunt procedures.

### *TipCAT Opportunities*

Microbot expects that its initial go-to-market strategy for the TipCAT will be to establish key hospital and clinic relationships in the field of colonoscopy that will allow Microbot to introduce and then diffuse the technology among colonoscopy experts and other stakeholders. Generally, Microbot expects the hospitals and clinics selected for the TipCAT clinical trials to also start using the product commercially, which will help to promote and support market uptake of the TipCAT product. Because Microbot expects the use of the TipCAT to increase the number of colonoscopy procedures that can be performed at any such facility, Microbot will seek to promote the technology among the doctors and experts involved in the distribution and buying groups within such selected partner hospitals.

## **Competition**

### *SCS Competitive Landscape*

Several academic research groups, such as at the New Jersey Institute of Technology, are currently researching sensing and obstruction-resistant catheter designs, and the Smart Sensors and Integrated Microsystems (SSIM) Program at Wayne State University has publicized that it is engaging in smart shunt development activity. However, based on its knowledge of the patented technologies, Microbot believes that these technologies are still early in the research and development cycle. The SCS also faces non-direct competition from Aqueduct Neurosciences, Inc., which is developing a non-shunt, electro-mechanical technology platform to control the draining of cerebrospinal fluid.

Microbot does not expect its SCS device to directly compete against shunt systems currently available in the market. The SCS device is designed to replace a component of existing shunt systems and is expected to be an aftermarket purchase that would be used to modify existing products by the end user. However, there can be no assurance that Microbot's product candidate will be accepted by the shunt market as an alternative component.

### *TipCAT Competitive Landscape*

The market for endoscopy products is highly competitive with several players operating both at a global and regional level. The leading players in the colonoscopy space are Pentax, Fuji and Olympus,

which dominate the U.S. market for reusable colonoscopes. However, Microbot believes that the most relevant competitors to TipCAT are smaller companies such as GI View and SMART Medical Systems, which produce disposable, self-propelled colonoscopes.

GI View produces a colonoscope with 360° omni-directional visualization and offers self-propelled intubation created using balloons and low pressure CO<sub>2</sub> gas. In addition, the GI View product is single use and disposable.

SMART Medical Systems' product, which, according to publicly available information is being commercialized by Pentax, is introduced by a physician through a standard colonoscope's tool channel and uses its balloon technology to anchor the bowel, which enables the colonoscope to be maneuvered beyond challenging lumen sections.

Microbot believes the TipCAT can successfully compete against its relevant competitors in that it offers all of the following attributes:

the ability to have varied dimensions during insertion and any subsequent point of a procedure, so as to accommodate the particular diameters of the organ at any moment, allows for the straightening of an organ's topography and improved visualization;

disposability, which protects against cross-contamination;

a working channel for therapeutic interventions (and additional visualization capabilities);

lower cost; and

a self-propelling mechanism, allowing for passage through challenging anatomical structures while eliminating tissue trauma.

Some of Microbot's competitors currently have significantly greater resources than Microbot does; have established relationships with healthcare professionals, customers and third-party payors; and have long-term contracts with group purchasing organizations in the United States. In addition, many of Microbot's competitors have established distributor networks, greater resources for product development, sales and marketing, additional lines of products and the ability to offer financial incentives such as rebates, bundled products or discounts on other product lines that Microbot cannot provide.

Microbot's products could also be rendered obsolete or uneconomical by technological advances developed in the future by existing or new competitors.

## **Intellectual Property**

### ***General***

Microbot is currently developing its first two product candidates, the SCS and TipCAT based on technological platforms licensed from TRDF, as further discussed below, and Microbot plans to develop other micro-robotic solutions through internal research and development to strengthen its intellectual property position, and continue exploring strategic collaborations and accretive acquisition opportunities. Microbot currently holds an intellectual

Edgar Filing: Microbot Medical Inc. - Form 8-K

property portfolio that includes 9 patent families, which include 8 patents granted in the US, 11 patents granted outside the US, and 17 patent applications pending worldwide, with other patent applications under development.



Microbot relies on intellectual property licensed or developed, including patents, trade secrets, technical innovations, laws of unfair competition and various licensing agreements to provide its future growth and to build its competitive position. As Microbot continues to expand its intellectual property portfolio, it is critical for Microbot to continue to invest in filing patent applications to protect its technology, inventions, and improvements.

Microbot relies on a combination of patents, trade secret, copyright and other intellectual property rights and measures to aggressively protect its intellectual property. It also relies on other forms of intellectual property, including trade secrets and know-how, to maintain its competitive position. Microbot requires its employees and consultants to execute confidentiality agreements in connection with their employment or consulting relationships with Microbot. Microbot also requires its employees and consultants who work on its product candidates to agree to disclose and assign to Microbot all inventions conceived during the term of their service, while using Microbot property, or which relates to Microbot's business.

Patent applications in the United States and in foreign countries are maintained in secrecy for a period of time after filing, which results in a delay between the actual discoveries and the filing of related patent applications and the time when discoveries are published in scientific and patent literature. Patents issued and patent applications filed relating to medical devices are numerous, and there can be no assurance that current and potential competitors and other third parties have not filed or in the future will not file applications for, or have not received or in the future will not receive, patents or obtain additional proprietary rights relating to product candidates, products, devices or processes used or proposed to be used by Microbot. Microbot believes that the technologies it employs in its products and systems do not infringe the valid claims of any third party patents. There can be no assurance, however, that third parties will not seek to assert that Microbot devices and systems infringe their patents or seek to expand their patent claims to cover aspects of Microbot's products and systems.

The medical device industry in general has been characterized by substantial litigation regarding patents and other intellectual property rights. Any such claims, regardless of their merit, could be time-consuming and expensive to respond to and could divert Microbot's technical and management personnel. Microbot may be involved in litigation to defend against claims of infringement by other patent holders, to enforce patents issued to Microbot, or to protect Microbot's trade secrets. If any relevant claims of third-party patents are upheld as valid and enforceable in any litigation or administrative proceeding, Microbot could be prevented from practicing the subject matter claimed in such patents, or would be required to obtain licenses from the patent owners of each such patent, or to redesign Microbot's products, devices or processes to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be available on terms acceptable to Microbot or Microbot would be successful in any attempt to redesign products or processes to avoid infringement. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent Microbot from manufacturing and selling its products.

Issued U.S. patents which cover Microbot's product candidates will expire between 2026 and 2031, excluding any patent term extensions that might be available following the grant of marketing authorization. Issued patents outside of the United States directed to Microbot's product candidates will expire between 2026 and 2032.

#### ***License Agreement with the Technion***

In June 2012, Microbot entered into a license agreement with Technion Research and Development Foundation Ltd., or TRDF, the technology transfer subsidiary of the Technion Institute of Technology, pursuant to which it obtained an exclusive, worldwide, royalty-bearing, sub-licensable

license to certain patents and inventions relating to the SCS and TipCAT technology platforms and invented by Professor Moshe Shoham, a director of the Company, and in certain circumstances other TRDF-related persons. Pursuant to the terms of the license agreement, in order to maintain the license with respect to each platform, Microbot must use commercially reasonable efforts to develop products covered by the license, including meeting certain agreed upon development milestones. The milestones for SCS include commencing initial studies in humans by December 2018 and commencing a full clinical trial, if necessary, by December 2019. The milestones for TipCAT include commencing initial studies in humans by December 2018 and commencing a full clinical trial, if necessary, by December 2020. Failure to meet any development milestone will give TRDF the right to terminate the license with respect to the technology underlying the missed milestone. Although Microbot expects to meet the milestone requirements, TRDF has demonstrated flexibility with respect to amending the terms of the license to extend the milestone dates.

As partial consideration for the grant of the licenses under the agreement, Microbot issued a number of shares to TRDF equal to 3% of its issued and outstanding shares at such time on a fully diluted basis. Such shares were initially subject to antidilution protections but are no longer subject to adjustment. In addition, as partial consideration for the licenses granted, Microbot agreed to pay TRDF royalties of between 1.5% and 3.0% of net sales of products covered by the licenses, subject to certain reductions, and certain percentages of amounts received by Microbot in the event of sublicensing.

In the case of termination of the license by Microbot without cause or by TRDF for cause, TRDF has the right to receive a non-exclusive license from Microbot with respect to improvements to the licensed technologies made by Microbot. In such cases, TRDF would pay a royalty of 10% of the income received by TRDF in connection its sublicensing of such patent right and related intellectual property. If the license from TRDF were to be terminated with respect with either of the technology platforms underlying the SCS or the TipCAT, Microbot would no longer be able to continue its development of the related product candidate. However, Microbot believes that its current intellectual property portfolio, and its ongoing efforts to expand into other micro-robotic surgical technologies, will give it the flexibility to shift its resources towards developing and commercializing related products.

## **Research and Development**

Microbot's research and development programs are generally pursued by engineers and scientists employed by Microbot in its offices in Israel on a full-time basis or as consultants, or through partnerships with industry leaders in manufacturing and design and researchers in academia. Microbot is also working with subcontractors in developing specific components of its technologies.

The primary objectives of Microbot's research and development efforts are to continue to introduce incremental enhancements to the capabilities of its candidate products and to advance the development of proposed products.

Microbot has received funds from the Office of the Chief Scientist in Israel, or OCS, for research and development activities. Microbot received a grant from the OCS in 2012, which grant reimbursed Microbot for 50% of its research and development expenses, up to \$764,466. This first grant from the OCS ended in 2014. After the expiration of the first grant, Microbot received approval for an additional grant from the OCS which reimbursed Microbot for 50% of its research and development expenses for the period from May 1, 2014 through September 30, 2015, up to \$924,166. After the expiration of the second grant, Microbot received an approval for a third grant from the Chief Scientist of Israel which reimbursed Microbot for 50% of its research and development expenses for the period from May 1, 2016 through April 30, 2017, up to \$1,026,050. Microbot expects to continue to access government funding in the future.

For the fiscal year ended December 31, 2015, Microbot incurred research and development expenses of \$822,759 compared to research and development expenses of \$836,698 for the fiscal year ended December 31, 2014.

Microbot has already made plans to develop a second version of its SCS device that will have an embedded controller and battery. This alternative design will allow the cleaning mechanism to be automatically activated, without the need for the patient's involvement in the activation process.

### **Manufacturing**

Microbot does not have any manufacturing facilities or manufacturing personnel. Microbot currently relies, and expects to continue to rely, on third parties for the manufacturing of its product candidates for preclinical and clinical testing, as well as for commercial manufacturing if its product candidates receive marketing approval.

### **Commercialization**

Microbot has not yet established a sales, marketing or product distribution infrastructure for its product candidates, which are still in development stages. Microbot plans to access the U.S. markets for hydrocephalus, NPH, and colonoscopy with its initial device offerings through strategic partnerships but may develop its own focused, specialized sales force or distribution channels once it has several commercialized products in its portfolio. Microbot has not yet developed a commercial strategy outside of the United States.

### **Government Regulation**

#### *General*

Microbot's medical technology products and operations are subject to extensive regulation in the United States and other countries. Most notably, if Microbot seeks to sell its products in the United States, its products will be subject to the Federal Food, Drug, and Cosmetic Act (FDCA) as implemented and enforced by the U.S. Food and Drug Administration (FDA). The FDA regulates the development, bench and clinical testing, manufacturing, labeling, storage, record-keeping, promotion, marketing, sales, distribution and post-market support and reporting of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. Regulatory policy affecting its products can change at any time.

Advertising and promotion of medical devices in the United States, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

Foreign countries where Microbot wishes to sell its products may require similar or more onerous approvals to manufacture or market its products. Government agencies in those countries also enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and market surveillance of medical device products. These regulatory requirements can change rapidly with relatively short notice.

Other regulations Microbot encounters in the United States and in other jurisdictions are the regulations that are common to all businesses, such as employment legislation, implied warranty laws, and environmental, health and safety standards, to the extent applicable. In the future, Microbot will also encounter industry-specific government regulations that would govern its products, if and when they are developed for commercial use.

*U.S. Regulation*

The FDA governs the following activities that Microbot performs, will perform, upon the clearance or approval of its product candidates, or that are performed on its behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

product design, and development;

product safety, testing, labeling and storage;

record keeping procedures; and

product marketing.

There are numerous FDA regulatory requirements governing the approval or clearance and subsequent commercial marketing of Microbot's products. These include:

the timely submission of product listing and establishment registration information, along with associated establishment user fees;

continued compliance with the Quality System Regulation, or QSR, which require specification developers and manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;

clearance or approval of product modifications that could significantly affect the safety or effectiveness of the device or that would constitute a major change in intended use;

Medical Device Reporting regulations (MDR), which require that manufacturers keep detailed records of investigations or complaints against their devices and to report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;

Edgar Filing: Microbot Medical Inc. - Form 8-K

adequate use of the Corrective and Preventive Actions process to identify and correct or prevent significant systemic failures of products or processes or in trends which suggest same;

post-approval restrictions or conditions, including post-approval study commitments;

post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and

notices of correction or removal and recall regulations.

Unless an exemption applies, before Microbot can commercially distribute medical devices in the United States, Microbot must obtain, depending on the classification of the device, either prior 510(k) clearance, 510(k) de-novo clearance or premarket approval (PMA), from the FDA. The FDA classifies medical devices into one of three classes based on the degree of risk associated with each medical device and the extent of regulatory controls needed to ensure the device's safety and effectiveness:

Class I devices, which are low risk and subject to only general controls (e.g., registration and listing, medical device labeling compliance, MDRs, Quality System Regulations, and prohibitions against adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements;

Class II devices, which are moderate risk and generally require 510(k) or 510(k) de-novo premarket clearance before they may be commercially marketed in the United States as well as general controls and potentially special controls like performance standards or specific labeling requirements; and

Class III devices, which are devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device.

Class III devices generally require the submission and approval of a PMA supported by clinical trial data.

Microbot expects the medical products in its pipeline currently to be classified as Class II. Class II devices are those for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and there is sufficient information to establish special controls. Special controls can include performance standards, post-market surveillance, patient histories and FDA guidance documents. Premarket review and clearance by the FDA for these devices is generally accomplished through the 510(k) or 510(k) de-novo premarket notification process. As part of the 510(k) or 510(k) de-novo notification process, FDA may require the following:

Development of comprehensive product description and indications for use.

Completion of extensive preclinical tests and preclinical animal studies, performed in accordance with the FDA's Good Laboratory Practice (GLP) regulations.

Comprehensive review of predicate devices and development of data supporting the new product's substantial equivalence to one or more predicate devices.

If appropriate and required, certain types of clinical trials (IDE submission and approval may be required for conducting a clinical trial in the US).

Clinical trials involve use of the medical device on human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices (GCPs), including the requirement that all research subjects provide informed consent for their participation in the clinical study. A written protocol with predefined end points, an appropriate sample size and pre-determined patient inclusion and exclusion criteria, is required before initiating and conducting a clinical trial. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's Investigational device Exemption, or IDE, regulations that among other things, govern investigational device labeling, prohibit promotion of the investigational device, and specify

recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a significant risk, as defined by the FDA, the agency requires the device sponsor to submit an IDE application, which must become effective prior to commencing human clinical trials. The

IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA denies the application or notifies the company that the investigation is on hold and may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE that requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but it must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

Assuming successful completion of all required testing, a detailed 510(k) premarket notification or 510(k) de-novo is submitted to the FDA requesting clearance to market the product. The notification includes all relevant data from pertinent preclinical and clinical trials, together with detailed information relating to the product's manufacturing controls and proposed labeling, and other relevant documentation.

A 510(k) clearance letter from the FDA will authorize commercial marketing of the device for one or more specific indications for use.

After 510(k) clearance, Microbot will be required to comply with a number of post-clearance requirements, including, but not limited to, Medical Device Reporting and complaint handling, and, if applicable, reporting of corrective actions. Also, quality control and manufacturing procedures must continue to conform to QSRs. The FDA periodically inspects manufacturing facilities to assess compliance with QSRs, which impose extensive procedural, substantive, and record keeping requirements on medical device manufacturers. In addition, changes to the manufacturing process are strictly regulated, and, depending on the change, validation activities may need to be performed. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with QSRs and other types of regulatory controls.

After a device receives 510(k) clearance from FDA, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use or technological characteristics, requires a new 510(k) clearance or could require a PMA. The FDA requires each manufacturer to make the determination of whether a modification requires a new 510(k) notification or PMA in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA for a particular change, the FDA may retroactively require the manufacturer to seek 510(k) clearance or PMA. The FDA can also require the manufacturer to cease U.S. marketing and/or recall the modified device until additional 510(k) clearance or PMA approval is obtained.

The FDA and the Federal Trade Commission, or FTC, will also regulate the advertising claims of Microbot's products to ensure that the claims Microbot makes are consistent with its regulatory clearances, that there is scientific data to substantiate the claims and that product advertising is neither false nor misleading.

To obtain 510(k) clearance, Microbot must submit a notification to the FDA demonstrating that its proposed device is substantially equivalent to a predicate device (i.e., a device that was in commercial distribution before May 28, 1976, a device that has been reclassified from Class III to Class I or Class II, or a 510(k)-cleared device). The FDA's 510(k) clearance process generally takes from three to 12 months from the date the application is submitted but also can take significantly longer. If the FDA determines that the device or its intended use is not substantially equivalent to a predicate device, the device is automatically placed into Class III, requiring the submission of a PMA.





There is no guarantee that the FDA will grant Microbot 510(k) clearance for its pipeline medical device products, and failure to obtain the necessary clearances for its products would adversely affect Microbot's ability to grow its business. Delays in receipt or failure to receive the necessary clearances, or the failure to comply with existing or future regulatory requirements, could reduce its business prospects.

Devices that cannot be cleared through the 510(k) process due to lack of a predicate device but would be considered low or moderate risk may be eligible for the 510(k) de-novo process. In 1997, the Food and Drug Administration Modernization Act, or FDAMA added the de novo classification pathway now codified in section 513(f)(2) of the FD&C Act. This law established an alternate pathway to classify new devices into Class I or II that had automatically been placed in Class III after receiving a Not Substantially Equivalent, or NSE, determination in response to a 510(k) submission. Through this regulatory process, a sponsor who receives an NSE determination may, within 30 days of receipt, request FDA to make a risk-based classification of the device through what is called a de novo request. In 2012, section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA), in order to provide a second option for de novo classification. Under this second pathway, a sponsor who determines that there is no legally marketed device upon which to base a determination of substantial equivalence can submit a de novo request to FDA without first submitting a 510(k).

In the event that Microbot receives a Not Substantially Equivalent determination for either of its device candidates in response to a 510(k) submission, the Microbot device may still be eligible for the 510(k) de-novo classification process.

Devices that cannot be cleared through the 510(k) or 510(k) de-novo classification process require the submission of a PMA. The PMA process is much more time consuming and demanding than the 510(k) notification process. A PMA must be supported by extensive data, including but not limited to data obtained from preclinical and/or clinical studies and data relating to manufacturing and labeling, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. After a PMA application is submitted, the FDA's in-depth review of the information generally takes between one and three years and may take significantly longer. If the FDA does not grant 510(k) clearance to its products, there is no guarantee that Microbot will submit a PMA or that if Microbot does, that the FDA would grant a PMA approval of Microbot's products, either of which would adversely affect Microbot's business.

#### *Foreign Regulation*

In addition to regulations in the United States, Microbot will be subject to a variety of foreign regulations governing clinical trials, marketing authorization and commercial sales and distribution of its products in foreign countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval or clearance. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

International sales of medical devices are subject to foreign governmental regulations which vary substantially from country to country. Whether or not Microbot obtains FDA approval or clearance for its products, Microbot will be required to make new regulatory submissions to the comparable regulatory authorities of foreign countries before Microbot can commence clinical trials or marketing of the product in such countries. The time required to obtain certification or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. Below are

summaries of the regulatory systems for medical devices in Europe and Israel, where Microbot currently anticipates marketing its products. However, its products may also be marketed in other countries that have different systems or minimal requirements for medical devices.

**Europe.** The primary regulatory body in Europe is the European Union, or E.U., which consists of 28 member states and has a coordinated system for the authorization of medical devices.

The E.U. has adopted legislation, in the form of directives to be implemented in each member state, concerning the regulation of medical devices within the European Union. The directives include, among others, the Medical Device Directive, or MDD, that establishes certain requirements with which medical devices must comply before they can be commercialized in the European Economic Area, or EEA (which comprises the member states of the E.U. plus Norway, Liechtenstein and Iceland). Under the MDD, medical devices are classified into four Classes, I, IIa, IIb, and III, with Class I being the lowest risk and Class III being the highest risk. However, the E.U. authorities, including the European Commission, do not have direct regulatory over medical device manufacturers under the MDD. Rather, the MDD directs E.U. Member States to implement laws and regulations consistent with the provisions set forth in the directive.

Under the MDD, to demonstrate compliance of a medical device with the essential requirements, manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. An accredited body known as a Notified Body, which is an entity designated by an E.U. Member State (or competent authority) to perform conformity assessments, will typically audit and examine the manufacturer's quality system for the production, quality, design and final inspection of the medical devices and review a Technical File containing technical documents regarding the device, including but limited to, detailed device description, manufacturing information, preclinical and clinical tests, risk analysis, compliance with essential requirements, etc., before issuing a certification demonstrating compliance with the essential requirements. Medical devices that comply with the essential requirements are entitled to bear the Conformité Européene, or CE Mark. Medical devices properly bearing the CE Mark may be commercially distributed throughout the EEA. Under the MDD, notified bodies are also charged with performing periodic inspections to verify that a manufacturer's quality system, particularly the production and quality controls, is adequately executed and maintained.

In addition, the MDD requires all medical device manufacturers to inform the competent authorities of their respective Member States of the address(es) of any business facilities and descriptions of any certified medical device products. The MDD also requires manufacturers to file vigilance reports in the event a device malfunction, deterioration in performance, or inadequate instructions or labeling results in, or could lead to, death or serious harm to a patient.

In September 2012, the European Commission published proposals for the revision of the EU regulatory framework for medical devices. The proposal would replace the MDD with a new regulation, the Medical Devices Regulation, or MDR. Unlike the MDD that must be implemented into national laws, the Medical Devices Regulation would be directly applicable in all EEA member states and so is intended to eliminate current national differences in regulation of medical devices. E.U. lawmakers published a revised draft of the proposed MDR in June 2016, which continues to be discussed within the Council of the European Union.

If finally adopted, the MDR is expected to enter into force in late 2016 and become applicable three years thereafter. The adoption of the MDR may, however, be materially delayed due to disagreements about specific portions of the regulation, as well as the implementation process. In its current form it would, among other things, impose additional reporting requirements on manufacturers of high risk medical devices, impose an obligation on manufacturers to appoint a qualified person



responsible for regulatory compliance, and provide for more strict clinical evidence requirements. These new rules and procedures will likely result in increased regulatory oversight of all medical devices marketed in the E.U., and this may, in turn, increase the costs, time and requirements that need to be met in order to place a medical devices on the EEA market.

Microbot intends to apply for the CE Mark for each of its medical device products. There is no guarantee that Microbot will be granted a CE Mark for all or any of its pipeline products and failure to obtain the CE Mark would adversely affect its ability to grow its business.

**Israel.** Israel's Medical Devices Law generally requires the registration of all medical products with the Ministry of Health, or MOH, Registrar as a precondition for production and distribution in Israel. Special exemptions may apply under limited circumstances and for purposes such as the provision of essential medical treatment, research and development of the medical device, and personal use, among others.

Registration of medical devices requires the submission of an application to the Ministry of Health Medical Institutions and Devices Licensing Department, or AMAR. An application for the registration of a medical device includes the following:

Name and address of the manufacturer, and of the importer as applicable;

Description of the intended use of the medical device and of its medical indications;

Technical details of the medical device and of its components, and in the event that the device or the components are not new, information should be provided on the date of renovation;

Certificate attesting to the safety of the device, issued by a competent authority of one of the following countries: Australia, Canada, European Community (EC), Member States (MSs), Israel, Japan, or the United States;

Information on any risk which may be associated with the use of the device (including precautionary measures to be taken);

Instructions for use of the device in Hebrew; the MOH may allow the instructions to be in English for certain devices;

Details of the standards to which the device complies;

Description of the technical and maintenance services, including periodic checks and inspections; and

Declaration, as appropriate: of the local manufacturer/importer, and of the foreign manufacturer.

If the application includes a certificate issued by a competent authority of one of the following recognized countries: Australia, Canada, European Community (CE) Member States (MSs), Japan, or the United States, the registration process is generally expedited, but could still take 6-9 months for approval. If such certificate is not available, the registration process will take significantly longer and a license is rarely issued. Furthermore, the MOH will determine what type of testing is needed. In general, in the case of Israeli manufactured devices that are not registered or authorized in any recognized country, the application requires presentation of a risk analysis, a clinical evaluation, a summary of the clinical trials, and expert opinions regarding the device's safety and effectiveness. Additional requirements may apply during the registration period, including follow-up reviews, to improve the quality and safety of the devices.

According to regulations issued by Israel's Minister of Health in June 2013, a decision on a request to register a medical device must be delivered by AMAR within 120 days from the date of the request, although this rarely occurs. The current rules for the registration of medical devices do not provide for an expedited approval process.

Once granted by the MOH, a license (marketing authorization) for a medical device is valid for five years from the date of registration of the device, except for implants with a life-supporting function, for which the validity is for only two years from the date of registration. Furthermore, the holder of the license, the Israeli Registration Holder, or IRH, must do the following to maintain its license:

Reside and maintain a place of business in Israel and serve as the regulatory representative.

Respond to questions from AMAR concerning the registered products.

Report adverse events to AMAR.

Renew the registration on time to keep the market approval active.

Comply with post-marketing requirements, including reporting of adverse and unexpected events occurring in Israel or in other countries where the device is in use.

Getting a device listed on Israel's four major Sick Funds (health insurance entities) is also necessary in order for Israeli hospitals and health care providers to order such products.

Microbot intends to apply for a license from the MOH for each of its medical devices. There is no guarantee that Microbot will be granted licenses for its pipeline products and failure to obtain such licenses would adversely affect its ability to grow its business.

## **Employees**

Microbot's Chief Executive Officer, President and Chairman, Harel Gadot, is based in Microbot's U.S. office located in Hingham, Massachusetts. Additionally, Microbot currently has five full-time employees and one part time employee based in its office located in Yokneam, Israel. These employees oversee day-to-day operations of the Company supporting management and leading engineering, manufacturing, intellectual property and administration functions of the Company. As required, Microbot also engages consultants to provide services to the Company, including regulatory, legal and corporate services. Microbot has no unionized employees.

Microbot currently plans to hire an additional 6-8 full-time employees within the next 12 months subject to the availability of funds, whose principal responsibilities will be the support of its operational, research and development, and clinical development activities.

## **Facilities**

Microbot's principal executive office is located at 175 Derby St., 27/1, Hingham, MA 02043. Microbot also has facilities in premises of approximately 1,840 square feet at 5 Hamada Street, 2<sup>nd</sup> Floor, Yokneam, Israel. Microbot plans to relocate to a larger facility in Israel within the next 12-18 months, which will provide the space and

infrastructure necessary to accommodate its development work based on its current operating plan. Microbot does not own any real property.



## Legal Matters

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm business.

We are not currently a party in any legal proceeding or governmental regulatory proceeding nor are we currently aware of any pending or potential legal proceeding or governmental regulatory proceeding proposed to be initiated against us that would have a material adverse effect on us or our business.

## RISK FACTORS

*The risks set forth below are not the only ones facing our Company. Additional risks and uncertainties may exist that could also adversely affect our business, financial condition, prospects and/or operations. If any of the following or other risks actually materialize, our business, financial condition, prospects and/or operations could suffer. In such event, the value of our securities could decline.*

### **Risks Relating to Microbot's Financial Position and Need for Additional Capital**

*Microbot has had no revenue and has incurred significant operating losses since inception and is expected to continue to incur significant operating losses following the Merger for the foreseeable future. The Company may never become profitable or, if achieved, be able to sustain profitability.*

Microbot has incurred significant operating losses since its inception and expects to incur significant losses for the foreseeable future as Microbot continues its preclinical and clinical development programs for its existing product candidates, SCS and TipCAT; its research and development of any other future product candidates; and all other work necessary to obtain regulatory clearances or approvals for its product candidates in the United States and other markets. In the future, Microbot intends to continue conducting micro-robotics research and development; performing necessary animal and clinical testing; working towards medical device regulatory compliance; and, if SCS, TipCAT or other future product candidates are approved or cleared for commercial distribution, engaging in appropriate sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in Microbot incurring further significant losses for the foreseeable future.

Microbot is a development-stage medical device company and currently generates no revenue from product sales, and may never be able to commercialize SCS, TipCAT or other future product candidates. Microbot does not currently have the required approvals or clearances to market or test in humans SCS, TipCAT or any other future product candidates and Microbot may never receive them. Microbot does not anticipate generating significant revenues until the Company can successfully develop, commercialize and sell products derived from its product pipeline, of which Microbot can give no assurance. Even if Microbot or any of its future development partners succeed in commercializing any of Microbot's product candidates, Microbot may never generate revenues significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with its product development pipeline and strategy, Microbot cannot accurately predict when it will achieve profitability, if ever. Failure to become and remain profitable would depress the value of the Company and could impair its ability to raise capital, which may force the Company to curtail or discontinue its research and development programs and/or day-to-day operations. Furthermore, there can be no assurance that profitability, if achieved, can be sustained on an ongoing basis.

***Microbot's business depends on the success of the SCS and the TipCAT, both of which are still in pre-clinical development. If Microbot is unable to obtain regulatory approval for or to successfully commercialize these products, its business will be materially harmed.***

To date, the primary focus of Microbot's product development has been on SCS, for the treatment of hydrocephalus and normal pressure hydrocephalus, or NPH, and TipCAT, a self-propelling, semi-disposable endoscope being developed initially for use in colonoscopy procedures. Successful continued development and ultimate regulatory approval or clearance of both SCS and TipCAT are critical to the future success of Microbot's business. Microbot has invested, and will continue to invest, a significant portion of its time and financial resources in the development, pre-clinical and clinical testing of and obtaining regulatory authorization for SCS and TipCAT. Microbot will need to raise sufficient funds to successfully complete its development of these products. The future regulatory and commercial success of SCS and TipCAT is subject to a number of risks, including the following:

Microbot may not have sufficient financial and other resources to complete the necessary clinical trials for SCS and TipCAT;

If clinical trials are required for FDA clearance or approval of SCS or TipCAT, Microbot may not be able to obtain adequate evidence from such clinical trials of safety and effectiveness in order to receive the applicable clearance or approval from the FDA; and

Microbot does not know the degree to which SCS or TipCAT will be accepted and adopted by physicians, patients and payors, even if approved or cleared by FDA for commercial marketing.

If Microbot is unable to successfully navigate these risks and achieve commercial success for its products, its business will be significantly harmed and Microbot may never become profitable.

***Microbot has a limited operating history, which may make it difficult to evaluate the prospects for the Company's future viability.***

Microbot has a limited operating history upon which an evaluation of its business plan or performance and prospects can be made. The business and prospects of Microbot must be considered in the light of the potential problems, delays, uncertainties and complications that may be encountered in connection with a newly established business. The risks include, but are not limited to, the possibility that Microbot will not be able to develop functional and scalable products, or that although functional and scalable, its products will not be economical to market; that its competitors hold proprietary rights that may preclude Microbot from marketing such products; that its competitors market a superior or equivalent product; that Microbot is not able to upgrade and enhance its technologies and products to accommodate new features and expanded service offerings; or the failure to receive necessary regulatory clearances or approvals for its products. To successfully introduce and market its products at a profit, Microbot must establish brand name recognition and competitive advantages for its products. There are no assurances that Microbot can successfully address these challenges. If it is unsuccessful, Microbot and its business, financial condition and operating results could be materially and adversely affected.



Microbot's operations to date have been limited to organizing the company, entering into licensing arrangements to initially obtain rights to its technologies, developing and securing its technologies, raising capital, developing regulatory and reimbursement strategies for its product candidates and preparing for pre-clinical and clinical trials of the SCS and TipCAT. Microbot has not yet demonstrated its ability to successfully complete development of any product candidate, obtain marketing clearance or approval, manufacture a commercial-scale product or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about Microbot's future success or viability may not be as accurate as they could be if Microbot had a longer operating history.

***Microbot's independent registered public accounting firm has noted that the continuation of Microbot as a business will be dependent on its ability to receive additional financing.***

Based on Microbot's limited operating history and the risks it faces, including uncertainties regarding the development of its product, Microbot's independent registered public accounting firm has included an explanatory paragraph in its report on Microbot's financial statements as of and for the years ended December 31, 2015 and December 31, 2014 elaborating on the business conditions Microbot faces. As Microbot expects to continue to incur significant operating costs and losses in connection with the development of its product and financing its business development operations, as of the date of the financial statements, the continuation of Microbot's activities and its obligations are dependent upon the receipt of financing from its shareholders or new investors.

***Microbot will need substantial additional funding. If Microbot is unable to raise capital when needed, it could be forced to delay, reduce or eliminate its product development programs or commercialization efforts.***

To date, Microbot Israel has funded its operations primarily through private placement offerings of debt and equity securities, grants and loans. From November 10, 2010 through September 30, 2016, Microbot Israel received: (i) approximately \$3.0 million from the issuance of Microbot Israel's series A preferred stock and the exercise of warrants to purchase Microbot Israel's series A preferred stock, (ii) approximately \$0.9 million for research and development activities as a grant from the Office of the Chief Scientist in Israel, and (iii) approximately \$1.57 million from shareholders of Microbot Israel pursuant to convertible loan agreements and exercise of warrants.

Microbot does not know when, or if, the Company will generate any revenue, but does not expect the Company to generate significant revenue unless and until it obtains regulatory clearance or approval of and commercializes one of its current or future product candidates. It is anticipated that the Company will continue to incur losses for the foreseeable future, and that losses will increase as the Company continues the development of, and seeks regulatory review of, its product candidates, and begins to commercialize any approved or cleared products following a successful regulatory review.

Microbot expects the research and development expenses of the Company to increase substantially in future periods as it conducts pre-clinical studies in large animals and potentially clinical trials for its product candidates, and especially if it initiates additional research programs for future product candidates. In addition, if the Company obtains marketing clearance or approval for any of its product candidates, it expects to incur significant commercialization expenses related to product manufacturing, marketing and sales. Furthermore, Microbot expects to incur additional costs associated with operating as a public company in the United States. Accordingly, the Company will need to obtain substantial additional funding in connection with its continuing operations. If the Company is unable to raise capital when needed or on attractive terms, it could be forced to delay, reduce or eliminate its research and development programs or any future commercialization efforts.

Microbot believes that the net cash of the Company that is available following completion of the Merger will be sufficient to fund the Company for at least 18 months and fund operations necessary to continue development activities of the SCS and TipCAT.

The Company may need to raise additional funds through equity offerings or otherwise in order to meet expected future liquidity needs, including the introduction of the SCS device into the hydrocephalus and NPH market, and introducing the TipCAT as a next-generation colonoscope. The Company's future capital requirements, generally, will depend on many factors, including:

the timing and outcomes of the product candidates' regulatory reviews, subsequent approvals or clearances, or other regulatory actions;

the costs, design, duration and any potential delays of the clinical trials that could be conducted at the FDA's request using Microbot's product candidates;

the costs of acquiring, licensing or investing in businesses, product candidates and technologies;

the costs to maintain, expand and defend the scope of Microbot's intellectual property portfolio;

the costs to secure or establish sales, marketing and commercial manufacturing capabilities or arrangements with third parties regarding same;

the Company's need and ability to hire additional management and scientific and medical personnel; and

the costs to operate as a public company in the United States, including the need to implement additional financial and reporting systems and other internal systems and infrastructure for the Company's business.

***Raising additional capital may cause dilution to the Company's investors, restrict its operations or require it to relinquish rights to its technologies or product candidates.***

Until such time, if ever, as the Company can generate substantial product revenues, it expects to finance its cash needs through a combination of equity offerings, licensing, collaboration or similar arrangements, grants and debt financings. The Company does not have any committed external source of funds other than a commitment by Alpha Capital Anstalt to invest an amount so that, with the funds from the Company's asset sale on November 29, 2016, we receive an aggregate of \$4.0 million under certain circumstances, which commitment has not been consummated as of the date of this Form 8-K. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interest of its stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holder of the Company's common stock. Debt financing, if available, may involve agreements that include covenants limiting or restricting the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or other distributions, selling or licensing intellectual property rights, and other operating restrictions that could adversely affect the Company's ability to conduct its business.

If the Company raises additional funds through licensing, collaboration or similar arrangements, it may have to relinquish valuable rights to its technologies, future revenue streams, research and development programs or product candidates or to grant licenses on terms that may not be favorable to the Company. If the Company is unable to raise additional funds through equity or debt financings or other arrangements when needed, it may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market product candidates that it would otherwise prefer to develop and market itself.

## Risks Relating to the Development and Commercialization of Microbot's Product Candidates

*Microbot's business depends heavily on the success of its lead product candidates, the SCS and the TipCAT. If Microbot is unable to commercialize the SCS or the TipCAT or experiences significant delays in doing so, Microbot's business will be materially harmed.*

Microbot expects the animal studies for SCS to start in the first quarter of 2017. Upon the completion of animal studies, Microbot may conduct clinical trials if they are requested by the FDA or if Microbot decides that the data from such trials would improve the marketability of the product candidate. The TipCAT is expected to enter animal studies in 2017. Upon the completion of animal studies, Microbot may conduct clinical trials if they are requested by the FDA or if Microbot decides that the data from such trials would improve the marketability of the product candidate. After all necessary clinical and performance data supporting the safety and effectiveness of each product candidate are collected, Microbot must still obtain FDA clearance or approval to market the device and those regulatory processes can take several months to several years to be completed. Therefore, Microbot's ability to generate product revenues will not occur for at least the next few years, if at all, and will depend heavily on the successful commercialization of SCS and TipCAT in their respective intended markets. The success of each of these product candidates will depend on a number of factors, including the following:

the Company's ability to obtain additional capital;

successful completion of animal studies and, if necessary, human clinical trials and the collection of sufficient data to demonstrate that the device is safe and effective for its intended use;

receipt of marketing approvals or clearances from FDA and other applicable regulatory authorities;

establishing commercial manufacturing arrangements with one or more third parties;

obtaining and maintaining patent and trade secret protections;

protecting Microbot's rights in its intellectual property portfolio;

establishing sales, marketing and distribution capabilities;

generating commercial sales of SCS and TipCAT, as applicable, if and when approved, whether alone or in collaboration with other entities;

acceptance of SCS and TipCAT, as applicable, if and when commercially launched, by the medical community, patients and third-party payors;

effectively competing with existing shunt and endoscope products on the market and any new competing products that may enter the market; and

maintaining quality and an acceptable safety profile of SCS and TipCAT, as applicable, following clearance or approval.

If Microbot does not achieve one or more of these factors in a timely manner or at all, Microbot could experience significant delays or an inability to successfully commercialize SCS and/or TipCAT, which would materially harm its business.



***Microbot's product candidates are subject to an uncertain and potentially lengthy domestic regulatory review process. If Microbot does not obtain and maintain the necessary regulatory authorizations from the Food and Drug Administration, Microbot will not be able to sell its product candidates in the United States.***

Microbot's product candidates and operations are subject to extensive regulation in the United States by the FDA under the agency's medical device authorities. The FDA regulates the development, bench and clinical testing, manufacturing, labeling, storage, record-keeping, promotion, marketing sales, distribution and post-market support and reporting of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. Microbot expects its product candidates to be classified as Class II. In order to market Class II products for use in the United States, Microbot must first obtain clearance from the FDA pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act. Clearance under Section 510(k) requires a demonstration that a new device is substantially equivalent to another device with 510(k) clearance or grandfathered status or to a device that was reclassified from Class III to Class II or Class I.

If the FDA determines that the device or its intended use is not substantially equivalent to a predicate device, the device is automatically placed into Class III, requiring the submission of a premarket approval application (PMA). There is no guarantee that the FDA will agree with Microbot's determination that a 510(k) notification is the appropriate regulatory pathway for its products, or that FDA will grant Microbot 510(k) clearance for its pipeline medical device products even if that pathway is accepted. Failure to obtain the necessary clearances for its products would adversely affect Microbot's ability to grow its business. Delays in receipt or failure to receive the necessary clearances, or the failure to comply with existing or future regulatory requirements, could reduce our business prospects.

Devices that cannot be cleared through the 510(k) process due to lack of a predicate device but would be considered low or moderate risk (in other words, they do not rise to the level of requiring the approval of a PMA) may be eligible for the 510(k) de novo classification process. If FDA determines that either of Microbot's product candidates is not eligible for a traditional 510(k), the Microbot device may still be eligible for the 510(k) de novo process.

Even if one or both of Microbot's product candidates receives 510(k) clearance from FDA, under either the traditional pathway or the de novo 510(k) pathway, any subsequent modification that could significantly affect the device's safety or effectiveness, or that would cause them to be marketed for additional indications for use, may require a new 510(k) clearance or a PMA for the modified products before Microbot will be permitted to market them in the United States. The FDA can require a manufacturer to cease U.S. marketing and/or recall the modified device until it is satisfied that the appropriate 510(k) clearance or PMA approval is obtained.

The FDA may not act favorably or quickly in its review of Microbot's 510(k), de novo 510(k), or PMA submissions, as applicable, or Microbot may encounter significant difficulties and costs in its efforts to obtain FDA clearance or approval, any of which could delay or preclude its sale of its product candidates in the United States. Furthermore, the FDA may request additional data or require Microbot to conduct further testing, or compile more data, including clinical data and clinical studies, in support of its 510(k) submission or potentially a de novo 510(k).

Moreover, the regulatory policies affecting Microbot's proposed product candidates can change at any time. The changes and their potential impact on Microbot's business cannot be accurately predicted. For example, in 2011, the FDA announced a Plan of Action to modernize and improve the FDA's premarket review of medical devices, and has implemented, and continues to implement, reforms intended to streamline the premarket review process. In addition, as part of the Food and Drug

Administration Safety and Innovation Act of 2012, Congress enacted several reforms through the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect both pre- and post-approval medical device regulation. Changes in the FDA 510(k) process could make clearance more difficult to obtain, increase delay, add uncertainty and have other significant adverse effects on Microbot's ability to obtain and maintain clearance for its product candidates.

The FDA may also, instead of accepting any kind of 510(k) submission, classify a product as high-risk and require Microbot to submit a PMA for the initial clearance, which is typically a much more complex, lengthy and burdensome application than a 510(k) submission. To support a PMA, the FDA would likely require that Microbot conduct one or more clinical studies to demonstrate that the device is safe and effective. In some cases such studies may be requested for a 510(k) or de novo 510(k) as well. Microbot may not be able to meet the requirements to obtain 510(k) clearance or PMA approval, in which case the FDA may not grant any necessary clearances or approvals. In addition, the FDA may place significant limitations upon the intended use of its product candidates as a condition to a 510(k) clearance or PMA approval. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following clearance or approval. Any delays or failure to obtain FDA clearance or approval of new products Microbot develops, any limitations imposed by the FDA on new product use or the costs of obtaining FDA clearance or approvals could have a material adverse effect on Microbot's business, financial condition and results of operations.

Failure to comply with the regulations or obtain the approvals described above could have a material adverse effect on Microbot's business, financial condition and results of operations. There can be no assurance that clinical trials will meet desired endpoints, produce meaningful or useful data and be free of unexpected adverse effects, and such uncertainty could preclude or delay market clearance or authorizations resulting in significant financial costs and reduced revenue.

***At this time, Microbot does not know whether the FDA will require it to submit clinical data in support of its future marketing applications for either product candidate.***

Microbot anticipates that each of its existing product candidates, SCS and TipCAT, will be classified by the FDA as Class II and thus be eligible for marketing pursuant to a cleared 510(k) notification. However, there is no guarantee that the FDA will agree with the Company's determination or that the FDA would accept the predicate devices that Microbot intends to submit in its 510(k) notifications in order to establish that its new device product is substantially equivalent to one or more predicate devices. The FDA also may request additional data in response to a 510(k) notification, or require Microbot to conduct further testing or compile more data in support of its 510(k) submission or de novo 510(k), as appropriate. Such additional data could include clinical data that must be derived from human clinical studies that are designed appropriately to address the potential questions from the FDA regarding a proposed product's safety or effectiveness.

In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, a company must, among other things, apply for and obtain Institutional Review Board, or IRB, approval of the proposed investigation. In addition, if the clinical study involves a significant risk (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an Investigational Device Exemption, or IDE, application. Microbot may not be able to obtain FDA and/or IRB approval to undertake clinical trials in the United States for any new devices Microbot intends to market in the United States in the future. Any type of clinical study in humans requires the investment of substantial expense, professional resources and time. Moreover, the timing of the commencement, continuation and completion of any future clinical

trial may be subject to significant delays attributable to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delay in or failure to obtain IRB approval to conduct a clinical trial at a prospective site, and shortages of supply in the investigational device.

The addition of one or more mandatory clinical trials to the development timeline for one or both Microbot product candidates would significantly increase the costs associated with developing and commercializing the product and delay the timing of U.S. regulatory authorization.

***Unsuccessful animal studies, clinical trials or procedures relating to product candidates under development could have a material adverse effect on Microbot's prospects.***

The regulatory approval process for new products and new indications for existing products requires extensive data and procedures, including the development of regulatory and quality standards and, potentially, certain clinical studies. Unfavorable or inconsistent data from current or future clinical trials or other studies conducted by Microbot or third parties, or perceptions regarding such data, could adversely affect Microbot's ability to obtain necessary device clearance or approval and the market's view of Microbot's future prospects. Failure to successfully complete these studies in a timely and cost-effective manner could have a material adverse effect on Microbot's prospects. Because animal trials, clinical trials and other types of scientific studies are inherently uncertain, there can be no assurance that these trials or studies will be completed in a timely or cost-effective manner or result in a commercially viable product. Clinical trials or studies may experience significant setbacks even if earlier preclinical or animal studies have shown promising results. Furthermore, preliminary results from clinical trials may be contradicted by subsequent clinical analysis. Results from clinical trials may also not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long-term studies or clinical experience, Microbot's business could be adversely affected. Clinical trials also may be suspended or terminated by us, the FDA or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks.

***Microbot has no prior experience in conducting clinical trials and will depend upon the ability of third parties, including contract research organizations, collaborative academic groups, future clinical trial sites and investigators, to conduct or to assist the Company in conducting clinical trials for its product candidates, if such trials become necessary.***

As a development-stage, pre-clinical company, Microbot has no prior experience in designing, initiating, conducting and monitoring human clinical trials, if data from such trials become necessary in order to obtain regulatory clearance or approval of our product candidates. Should the FDA or another regulatory agency in a foreign market request clinical data to support the safety and effectiveness of Microbot's product candidates, Microbot will depend upon its ability and/or the ability of future collaborators, contract research organizations, clinical trial sites and investigators to successfully design, initiate, conduct and monitor such clinical trials.

Failure by Microbot or by any of these future collaborating parties to timely and effectively initiate, conduct and monitor a future clinical trial could significantly delay or materially impair Microbot's ability to complete those clinical trials and/or obtain regulatory clearance or approval of its product candidates and, consequently, could delay or materially impair its ability to generate revenues from the commercialization of those products.

***If the commercial opportunity for SCS and TipCAT is smaller than Microbot anticipates, Microbot's future revenue from SCS and TipCAT will be adversely affected and Microbot's business will suffer.***

If the size of the commercial opportunities in any of Microbot's target markets is smaller than Microbot anticipates, Microbot may not be able to achieve profitability and growth. Microbot is developing SCS as a device for the treatment of hydrocephalus and NPH and is developing TipCAT as an endoscopic tool, with colonoscopy as the most immediate application of the TipCAT technology. Microbot expects its future revenues to be primarily derived from the sales of the SCS and TipCAT, neither of which has undergone an FDA pre-market review process necessary to commercialize the product candidate in the United States. It is difficult to predict the penetration, future growth rate or size of the market for Microbot's product candidates.

The commercial success of the SCS and TipCAT will require broad acceptance of the devices by the doctors and other medical professionals who specialize in the procedures targeted by each device, a limited number of whom may be able to influence device selection and purchasing decisions. If Microbot's technologies are not broadly accepted and perceived as having significant advantages over existing medical devices, then Microbot will not meet its business objectives. Such perceptions are likely to be based on a determination by medical facilities and physicians that Microbot's product candidates are safe and effective, are cost-effective in comparison to existing devices, and represent acceptable methods of treatment. Microbot cannot assure that it will be able to establish the relationships and arrangements with medical facilities and physicians necessary to support the market uptake of its product candidates. In addition, its competitors may develop new technologies for the same markets Microbot is targeting that are more attractive to medical facilities and physicians. If doctors and other medical professionals do not consider Microbot product candidates to be suitable for application in the procedures we are targeting and an improvement over the use of existing or competing products, Microbot's business goals will not be realized.

***Customers will be unlikely to buy the SCS or the TipCAT unless Microbot can demonstrate that they can be produced for sale to consumers at attractive prices.***

To date, Microbot has focused primarily on research and development of the first generation versions of the SCS and the TipCAT. Consequently, Microbot has no experience in manufacturing its product candidates, and intends to manufacture its product candidates through third-party manufacturers. Microbot can offer no assurance that either it or its manufacturing partners will develop efficient, automated, low-cost manufacturing capabilities and processes to meet the quality, price, engineering, design and production standards or production volumes required to successfully mass produce its commercial products. Even if its manufacturing partners are successful in developing such manufacturing capability and quality processes, including the assurance of GMP-compliant device manufacturing, there can be no assurance that Microbot can timely meet its product commercialization schedule or the production and delivery requirements of potential customers. A failure to develop such manufacturing processes and capabilities could have a material adverse effect on Microbot's business and financial results.

The proposed price of Microbot's product candidates, once approved for sale, will be dependent on material and other manufacturing costs. Microbot cannot offer any assurances that its manufacturing partner will be able to manufacture its product candidates at a competitive price or that achieving cost reductions will not cause a reduction in the performance, reliability and longevity of its product candidates.

***Microbot has relied on, and intends to continue to rely on, third-party manufacturers to produce its product candidates.***

Microbot currently relies, and expects to rely for the foreseeable future, on third-party manufacturers to produce and supply its product candidates, and it expects to rely on third parties to manufacture the commercialized products as well, should they receive the necessary regulatory clearance or approval. Reliance on third-party manufacturers entails risks to which Microbot would not be subject if Microbot manufactured its product candidates or future commercial products itself, including:

limitations on supply availability resulting from capacity, internal operational problems or scheduling constraints of third parties;

potential regulatory non-compliance or other violations by the third-party manufacturer that could result in quality assurance issues or government enforcement action that has a negative effect on Microbot's product candidates and distribution strategy;

the possible breach of manufacturing agreements by third parties because of various factors beyond Microbot's control; and

the possible termination or non-renewal of manufacturing agreements by third parties for various reasons beyond Microbot's control, at a time that is costly or inconvenient to Microbot.

If Microbot is not able to maintain its key manufacturing relationships, Microbot may fail to find replacement manufacturers or develop its own manufacturing capabilities, which could delay or impair Microbot's ability to obtain regulatory clearance or approval for its product candidates and could substantially increase its costs or deplete profit margins, if any. If Microbot does find replacement manufacturers, Microbot may not be able to enter into agreements with them on terms and conditions favorable to it and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

***If Microbot's product candidates are not considered to be a safe and effective alternative to existing technologies, Microbot will not be commercially successful.***

The SCS and TipCAT rely on new technologies, and Microbot's success will depend on acceptance of these technologies by the medical community as safe, clinically effective, cost effective and a preferred device as compared to products of its competitors. Microbot does not have long-term data regarding efficacy, safety and clinical outcomes associated with the use of SCS or TipCAT. Any data that is generated in the future may not be positive or may not support the product candidates' regulatory dossiers, which would negatively affect market acceptance and the rate at which its product candidates are adopted. Equally important will be physicians' perceptions of the safety of Microbot's product candidates because Microbot's technologies are relatively new. If, over the long term, Microbot's product candidates do not meet surgeons' expectations as to safety, efficacy and ease of use, they may not become widely adopted.

Market acceptance of Microbot's product candidates will also be affected by other factors, including Microbot's ability to convince key opinion leaders to provide recommendations regarding its product candidates; convince distributors that its technologies are attractive alternatives to existing and competing technologies; supply and service sufficient quantities of products directly or through marketing alliances; and price products competitively in light of the current

macroeconomic environment, which is becoming increasingly price sensitive.

***Microbot may be subject to penalties and may be precluded from marketing its product candidates if Microbot fails to comply with extensive governmental regulations.***

Microbot believes that its medical device product candidates will be categorized as Class II devices, which typically require a 510(k) or 510(k) de-novo premarket submission to the FDA. However, the FDA has not made any determination about whether Microbot's medical product candidates are Class II medical devices and may disagree with that classification. If the FDA determines that Microbot's product candidates should be reclassified as Class III medical devices, Microbot could be precluded from marketing the devices for clinical use within the United States for months, years or longer, depending on the specifics of the change in classification. Reclassification of any of Microbot's product candidates as Class III medical devices could significantly increase Microbot's regulatory costs, including the timing and expense associated with required clinical trials and other costs.

The FDA and non-U.S. regulatory authorities require that Microbot product candidates be manufactured according to rigorous standards. These regulatory requirements significantly increase Microbot's production costs, which may prevent Microbot from offering products within the price range and in quantities necessary to meet market demands. If Microbot or one of its third-party manufacturers changes an approved manufacturing process, the FDA may need to review the process before it may be used. Failure to comply with applicable pre-market and post-market regulatory requirements could subject Microbot to enforcement actions, including warning letters, fines, injunctions and civil penalties, recall or seizure of its products, operating restrictions, partial suspension or total shutdown of its production, and criminal prosecution.

***If Microbot is not able to both obtain and maintain adequate levels of third-party reimbursement for procedures involving its product candidates after they are approved for marketing and launched commercially, it would have a material adverse effect on Microbot's business.***

Healthcare providers and related facilities are generally reimbursed for their services through payment systems managed by various governmental agencies worldwide, private insurance companies, and managed care organizations. The manner and level of reimbursement in any given case may depend on the site of care, the procedure(s) performed, the final patient diagnosis, the device(s) utilized, available budget, or a combination of these factors, and coverage and payment levels are determined at each payor's discretion. The coverage policies and reimbursement levels of these third-party payors may impact the decisions of healthcare providers and facilities regarding which medical products they purchase and the prices they are willing to pay for those products. Microbot cannot assure you that its sales will not be impeded and its business harmed if third-party payors fail to provide reimbursement for Microbot products that healthcare providers view as adequate.

In the United States, Microbot expects that its product candidates, once approved, will be purchased primarily by medical institutions, which then bill various third-party payors, such as the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program through Medicare Administrative Contractors, and other government health care programs and private insurance plans, for the healthcare products and services provided to their patients. The process involved in applying for coverage and incremental reimbursement from CMS is lengthy and expensive. Moreover, many private payors look to CMS in setting their reimbursement policies and amounts. If CMS or other agencies limit coverage for procedures utilizing Microbot's products or decrease or limit reimbursement payments for doctors and hospitals utilizing Microbot's products, this may affect coverage and reimbursement determinations by many private payors.

If a procedure involving a medical device is not reimbursed separately by a government or private insurer, then a medical institution would have to absorb the cost





of Microbot's products as part of the cost of the procedure in which the products are used. At this time, Microbot does not know the extent to which medical institutions would consider insurers' payment levels adequate to cover the cost of its products. Failure by hospitals and surgeons to receive an amount that they consider to be adequate reimbursement for procedures in which Microbot products are used could deter them from purchasing Microbot products and limit sales growth for those products.

Microbot has no control over payor decision-making with respect to coverage and payment levels for its medical device product candidates, once they are approved. Additionally, Microbot expects many payors to continue to explore cost-containment strategies (e.g., comparative and cost-effectiveness analyses, so-called pay-for-performance programs implemented by various public government health care programs and private third-party payors, and expansion of payment bundling initiatives, and other such methods that shift medical cost risk to providers) that may potentially impact coverage and/or payment levels for Microbot's current product candidates or products Microbot develops in the future.

As Microbot's product offerings are used across diverse healthcare settings, they will be affected to varying degrees by the different payment systems.

***Clinical outcome studies for the SCS may not provide sufficient data to make Microbot's product candidates the standard of care.***

Microbot's business plan relies on the broad adoption by surgeons of the SCS for primary shunt placement procedures to prevent shunt occlusions. Although Microbot believes the occurrence of shunt occlusion complications is well known among physicians practicing in the relevant medical fields, SCS may be adopted for replacement shunt surgeries only. Neurosurgeons may adopt SCS for primary shunt placement procedures only upon additional clinical studies with longer follow up periods, if at all. It may also be necessary to provide outcome studies on the preventative capabilities of the SCS in order to convince the medical community of its safety and efficacy. Clinical studies may not show an advantage in SCS based procedures in a timely manner, or at all, and outcome studies have not been designed at this time, and may be too large and too costly for Microbot to conduct. Both situations could prevent broad adoption of the SCS and materially impact Microbot's business.

***Microbot products may in the future be subject to mandatory product recalls that could harm its reputation, business and financial results.***

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could pose a risk of injury to patients. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death, although in most cases this mandatory recall authority is not used because manufacturers typically initiate a voluntary recall when a device violation is discovered. In addition, foreign governmental bodies have the authority to require the recall of Microbot products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by Microbot or one of its distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any Microbot products would divert managerial and financial resources and have an adverse effect on Microbot's financial condition and results of operations, and any future recall announcements could harm Microbot's reputation with customers and negatively affect its sales. In addition, the FDA could take enforcement action, including any of the following sanctions for failing to timely report a recall to the FDA:

untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

detention or seizure of Microbot products;

operating restrictions or partial suspension or total shutdown of production;

refusing or delaying requests for 510(k) clearance or premarket approval of new products or modified products;

withdrawing 510(k) clearances or other types of regulatory authorizations -that have already been granted;

refusing to grant export approval for Microbot products; or

criminal prosecution.

***If Microbot's future commercialized products cause or contribute to a death or a serious injury, Microbot will be subject to Medical Device Reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.***

Under FDA regulations, Microbot will be required to report to the FDA any incident in which a marketed medical device product may have caused or contributed to a death or serious injury or in which a medical device malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in European Union markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred.

Microbot anticipates that in the future it is likely that we may experience events that would require reporting to the FDA pursuant to the Medical Device Reporting (MDR) regulations. Any adverse event involving a Microbot product could result in future voluntary corrective actions, such as product actions or customer notifications, or agency actions, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending Microbot in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

***Microbot could be exposed to significant liability claims if Microbot is unable to obtain insurance at acceptable costs and adequate levels or otherwise protect itself against potential product liability claims.***

The testing, manufacture, marketing and sale of medical devices entail the inherent risk of liability claims or product recalls. Product liability insurance is expensive and may not be available on acceptable terms, if at all. A successful product liability claim or product recall could inhibit or prevent the successful commercialization of Microbot's products, cause a significant financial burden on Microbot, or both, which in any case could have a material adverse effect on Microbot's business and financial condition.

***The results of Microbot's research and development efforts are uncertain and there can be no assurance of the commercial success of Microbot's product candidates.***

Microbot believe that its success will depend in part on its ability to expand its product offerings and continue to improve its existing product candidates in response to changing technologies, customer demands and competitive pressures. As such, Microbot expects to continue dedicating significant



resources in research and development. The product candidates and services being developed by Microbot may not be technologically successful. In addition, the length of Microbot's product candidates and service development cycle may be greater than Microbot originally expected.

***If Microbot fail to retain certain of its key personnel and attract and retain additional qualified personnel, Microbot might not be able to pursue its growth strategy effectively.***

Microbot is dependent on its senior management, in particular Harel Gadot, Microbot's Chairman, President and Chief Executive Officer. Although Microbot believes that its relationship with members of its senior management is positive, there can be no assurance that the services of any of these individuals will continue to be available to Microbot in the future. Microbot's future success will depend in part on its ability to retain its management and scientific teams, to identify, hire and retain additional qualified personnel with expertise in research and development and sales and marketing, and to effectively provide for the succession of senior management, when necessary. Competition for qualified personnel in the medical device industry is intense and finding and retaining qualified personnel with experience in the industry is very difficult. Microbot believes that there are only a limited number of individuals with the requisite skills to serve in key positions at Microbot, particularly in Israel, and it competes for key personnel with other medical equipment and technology companies, as well as research institutions.

Microbot does not carry, and does not intend to carry, any key man life insurance policies on any of its existing executive officers.

#### **Risks Relating to International Business**

***If Microbot fails to obtain regulatory clearances in other countries for its product candidates under development, Microbot will not be able to commercialize these product candidates in those countries.***

In order for Microbot to market its product candidates in countries other than the United States, Microbot must comply with the safety and quality regulations in such countries.

In Europe, these regulations, including the requirements for approvals, clearance or grant of Conformité Européenne, or CE, Certificates of Conformity and the time required for regulatory review, vary from country to country. Failure to obtain regulatory approval, clearance or CE Certificates of Conformity (or equivalent) in any foreign country in which Microbot plans to market its product candidates may harm its ability to generate revenue and harm its business. Approval and CE marking procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval or CE Certificate of Conformity in other countries might differ from that required to obtain FDA clearance. The regulatory approval or CE marking process in other countries may include all of the risks detailed above regarding FDA clearance in the United States. Regulatory approval or the CE marking of a product candidate in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval or a CE Certificate of Conformity in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval or a CE Certificate of Conformity in other countries or any delay or setback in obtaining such approval could have the same adverse effects described above regarding FDA clearance in the United States.

Microbot cannot be certain that it will be successful in complying with the requirements of the CE Certificate of Conformity and receiving a CE Mark for its product candidates or in continuing to meet the requirements of the Medical Devices Directive in the European Economic Area (EEA).

Israel's Medical Devices Law generally requires the registration of all medical products with the Ministry of Health, or MOH, Registrar through the submission of an application to the Ministry of Health Medical Institutions and Devices Licensing Department, or AMAR. If the application includes a certificate issued by a competent authority of a recognized country, which includes Australia, Canada, the European Community Member States, Japan or the United States, the registration process is expedited, but is generally still expected to take 6 to 9 months for approval. If certification from a recognized country is not available, the registration process takes significantly longer and a license is rarely issued under such circumstances, as the MOH may require the presentation of significant additional clinical data. Once granted, a license (marketing authorization) for a medical device is valid for five years from the date of registration of the device, except for implants with a life-supporting function, for which the validity is for only two years from the date of registration. Furthermore, the holder of the license must meet several additional requirements to maintain the license. Microbot cannot be certain that it will be successful in applying for a license from the MOH for its product candidates.

***Microbot operations in international markets involve inherent risks that Microbot may not be able to control.***

Microbot's business plan includes the marketing and sale of its proposed product candidates internationally, and specifically in Europe and Israel. Accordingly, Microbot's results could be materially and adversely affected by a variety of factors relating to international business operations that it may or may not be able to control, including:

adverse macroeconomic conditions affecting geographies where Microbot intends to do business;

foreign currency exchange rates;

political or social unrest or economic instability in a specific country or region;

higher costs of doing business in certain foreign countries;

infringement claims on foreign patents, copyrights or trademark rights;

difficulties in staffing and managing operations across disparate geographic areas;

difficulties associated with enforcing agreements and intellectual property rights through foreign legal systems;

trade protection measures and other regulatory requirements, which affect Microbot's ability to import or export its product candidates from or to various countries;

adverse tax consequences;

unexpected changes in legal and regulatory requirements;

military conflict, terrorist activities, natural disasters and medical epidemics; and

Microbot's ability to recruit and retain channel partners in foreign jurisdictions.

---

***Microbot's financial results may be affected by fluctuations in exchange rates and Microbot's current currency hedging strategy may not be sufficient to counter such fluctuations.***

Microbot's financial statements are denominated in U.S. dollars and the financial results of the Company are expected to be denominated in U.S. dollars, while a significant portion of Microbot's business is conducted, and a substantial portion of its operating expenses are payable, in currencies other than the U.S. dollar. Exchange rate fluctuations may have an adverse impact on Microbot's future revenues or expenses as presented in the financial statements. Microbot may in the future use financial instruments, such as forward foreign currency contracts, in its management of foreign currency exposure. These contracts would primarily require Microbot to purchase and sell certain foreign currencies with or for U.S. dollars at contracted rates. Microbot may be exposed to a credit loss in the event of non-performance by the counterparties of these contracts. In addition, these financial instruments may not adequately manage Microbot's foreign currency exposure. Microbot's results of operations could be adversely affected if Microbot is unable to successfully manage currency fluctuations in the future.

### **Risks Relating to Microbot's Intellectual Property**

***Microbot's right to develop and commercialize its existing product candidates are subject to the terms and condition of a license granted to Microbot by Technion Research and Development Foundation Ltd and termination of the license with respect to one or both of the technology platforms underlying the product candidates would result in Microbot ceasing its development efforts for the applicable product candidate(s).***

Microbot entered into a license agreement with Technion Research and Development Foundation Ltd., or TRDF, in 2012 pursuant to which Microbot obtained an exclusive, worldwide, royalty-bearing, sub-licensable license to certain patents and inventions relating to the SCS and TipCAT technology platforms. Pursuant to the terms of the license agreement, in order to maintain the license with respect to each platform, Microbot must use commercially reasonable efforts to develop products covered by the license, including meeting certain agreed upon development milestones. TRDF has the option to terminate a license granted with respect to a particular technology in the event Microbot fails to meet a development milestone associated with such technology. Therefore, the failure to meet development milestones may lead to a complete termination of the applicable license agreement and result in Microbot ceasing its development efforts for the applicable product candidate. The milestones for SCS include commencing initial studies in humans by December 2018 and commencing a clinical trial, if necessary, by December 2019. The milestones for TipCAT include commencing initial studies in humans by December 2018 and commencing a full clinical trial, if necessary, by December 2020. Failure to meet any development milestone will give TRDF the right to terminate the license with respect to the technology underlying the missed milestone. Although Microbot expects to meet the milestone requirements, TRDF has demonstrated flexibility with respect to amending the terms of the license to extend the milestone dates.

Under the license agreement, Microbot is also subject to various other obligations, including obligations with respect to payment upon the achievement of certain milestones and royalties on product sales. TRDF may terminate the license agreement under certain circumstances, including material breaches by Microbot or under certain bankruptcy or insolvency events. In the case of termination of the license by Microbot without cause or by TRDF for cause, TRDF has the right to receive a non-exclusive license from Microbot with respect to improvements to the licensed technologies made by Microbot.

If TRDF were to terminate the license agreement or if Microbot was to otherwise lose the ability to exploit the licensed patents, Microbot's competitive advantage could be reduced or terminated, and Microbot will likely not be able to find a source to replace the licensed technology.





However, if there is any future dispute between Microbot and TRDF regarding the respective parties' rights under the license agreement, Microbot's ability to develop and commercialize the SCS and TipCAT may be materially harmed.

***Microbot may not meet its product candidates' development and commercialization objectives in a timely manner or at all.***

Microbot has established internal goals, based upon expectations with respect to its technologies, which Microbot has used to assess its progress toward developing its product candidates. These goals relate to technology and design improvements as well as to dates for achieving specific development results. If the product candidates exhibit technical defects or are unable to meet cost or performance goals, Microbot's commercialization schedule could be delayed and potential purchasers of its initial commercialized products may decline to purchase such products or may opt to pursue alternative products, which would materially harm its business.

***Intellectual property litigation and infringement claims could cause Microbot to incur significant expenses or prevent Microbot from selling certain of its product candidates.***

The medical device industry is characterized by extensive intellectual property litigation. From time to time, Microbot might be the subject of claims by third parties of potential infringement or misappropriation. Regardless of outcome, such claims are expensive to defend and divert the time and effort of Microbot's management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against Microbot could result in its payment of significant monetary damages and/or royalty payments or negatively impact its ability to sell current or future products in the affected category and could have a material adverse effect on its business, cash flows, financial condition or results of operations.

***If Microbot or TRDF are unable to protect the patents or other proprietary rights relating to Microbot's product candidates, or if Microbot infringes on the patents or other proprietary rights of others, Microbot's competitiveness and business prospects may be materially damaged.***

Microbot's success depends on its ability to protect its intellectual property (including its licensed intellectual property) and its proprietary technologies. Microbot's commercial success depends in part on its ability to obtain and maintain patent protection and trade secret protection for its product candidates, proprietary technologies, and their uses, as well as its ability to operate without infringing upon the proprietary rights of others.

Microbot currently holds, through licenses or otherwise, an intellectual property portfolio that includes U.S. and international patents and pending patents, and other patents under development. Microbot intends to continue to seek legal protection, primarily through patents, including the TRDF licensed patents, for its proprietary technology. Seeking patent protection is a lengthy and costly process, and there can be no assurance that patents will be issued from any pending applications, or that any claims allowed from existing or pending patents will be sufficiently broad or strong to protect its proprietary technology. There is also no guarantee that any patents Microbot holds, through licenses or otherwise, will not be challenged, invalidated or circumvented, or that the patent rights granted will provide competitive advantages to Microbot. Microbot's competitors have developed and may continue to develop and obtain patents for technologies that are similar or superior to Microbot's technologies. In addition, the laws of foreign jurisdictions in which Microbot develops, manufactures or sells its product candidates may not protect Microbot's intellectual property rights to the same extent as do the laws of the United States.

Adverse outcomes in current or future legal disputes regarding patent and other intellectual property rights could result in the loss of Microbot's intellectual property rights, subject Microbot to significant liabilities to third parties, require Microbot to seek licenses from third parties on terms that may not be reasonable or favorable to Microbot, prevent Microbot from manufacturing, importing or selling its product candidates, or compel Microbot to redesign its product candidates to avoid infringing third parties' intellectual property. As a result, Microbot may be required to incur substantial costs to prosecute, enforce or defend its intellectual property rights if they are challenged. Any of these circumstances could have a material adverse effect on Microbot's business, financial condition and resources or results of operations.

Microbot has the first right, but not the obligation, to control the prosecution, maintenance or enforcement of the licensed patents from TRDF. However, there may be situations in which Microbot will not have control over the prosecution, maintenance or enforcement of the patents that Microbot licenses, or may not have sufficient ability to consult and input into the patent prosecution and maintenance process with respect to such patents. If Microbot does not control the patent prosecution and maintenance process with respect to the TRDF licensed patents, TRDF may elect to do so but may fail to take the steps that are necessary or desirable in order to obtain, maintain and enforce the licensed patents.

Microbot's ability to develop intellectual property depends in large part on hiring, retaining and motivating highly qualified design and engineering staff and consultants with the knowledge and technical competence to advance its technology and productivity goals. To protect Microbot's trade secrets and proprietary information, Microbot has entered into confidentiality agreements with its employees, as well as with consultants and other parties. If these agreements prove inadequate or are breached, Microbot's remedies may not be sufficient to cover its losses.

***Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may result in Microbot's payment of significant monetary damages or impact offerings in its product portfolios.***

Microbot's long-term success largely depends on its ability to market technologically competitive product candidates. If Microbot fails to obtain or maintain adequate intellectual property protection, it may not be able to prevent third parties from using its proprietary technologies or may lose access to technologies critical to our product candidates. Also, Microbot currently pending or future patent applications may not result in issued patents, and issued patents are subject to claims concerning priority, scope and other issues.

Furthermore, Microbot has not filed applications for all of our patents internationally and it may not be able to prevent third parties from using its proprietary technologies or may lose access to technologies critical to its product candidates in other countries.

### **Risks Relating to Operations in Israel**

***Microbot has facilities located in Israel, and therefore, political conditions in Israel may affect Microbot's operations and results.***

Microbot has facilities located in Israel. In addition, half of its directors are residents of Israel. Accordingly, political, economic and military conditions in Israel will directly or indirectly affect Microbot's operations and results. Since the establishment of the State of Israel, a number of armed conflicts have taken place between Israel and its Arab neighbors. An ongoing state of hostility, varying in degree and intensity has led to security and economic problems for Israel. For a number of years there have been continuing hostilities between Israel and the Palestinians. This includes hostilities with the Islamic movement Hamas in the Gaza Strip, which have adversely affected the peace process and at times



resulted in armed conflicts. Such hostilities have negatively influenced Israel's economy as well as impaired Israel's relationships with several other countries. Israel also faces threats from Hezbollah militants in Lebanon, from ISIS and rebel forces in Syria, from the government of Iran and other potential threats from additional countries in the region. Moreover, some of Israel's neighboring countries have recently undergone or are undergoing significant political changes. These political, economic and military conditions in Israel could have a material adverse effect on Microbot's business, financial condition, results of operations and future growth.

***Political relations could limit Microbot's ability to sell or buy internationally.***

Microbot could be adversely affected by the interruption or reduction of trade between Israel and its trading partners. Some countries, companies and organizations continue to participate in a boycott of Israeli firms and others doing business with Israel, with Israeli companies or with Israeli-owned companies operating in other countries. Foreign government defense export policies towards Israel could also make it more difficult for us to obtain the export authorizations necessary for Microbot's activities. Also, over the past several years there have been calls in Europe and elsewhere to reduce trade with Israel. There can be no assurance that restrictive laws, policies or practices directed towards Israel or Israeli businesses will not have an adverse impact on Microbot's business.

***Israel's economy may become unstable.***

From time to time, Israel's economy may experience inflation or deflation, low foreign exchange reserves, fluctuations in world commodity prices, military conflicts and civil unrest. For these and other reasons, the government of Israel has intervened in the economy employing fiscal and monetary policies, import duties, foreign currency restrictions, controls of wages, prices and foreign currency exchange rates and regulations regarding the lending limits of Israeli banks to companies considered to be in an affiliated group. The Israeli government has periodically changed its policies in these areas. Reoccurrence of previous destabilizing factors could make it more difficult for Microbot to operate its business and could adversely affect its business.

***Exchange rate fluctuations between the U.S. dollar and the NIS currencies may negatively affect Microbot's operating costs.***

A significant portion of Microbot's expenses is paid in New Israeli Shekels, or NIS, but its financial statements are denominated in U.S. dollars. As a result, Microbot is exposed to the risks that the NIS may appreciate relative to the U.S. dollar, or the NIS instead devalues relative to the U.S. dollar, and the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the U.S. dollar cost of Microbot's operations in Israel would increase and Microbot's U.S. dollar-denominated results of operations would be adversely affected. Microbot cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the U.S. dollar.

Microbot's primary expenses paid in NIS that are not linked to the U.S. dollar are employee expenses in Israel and lease payments on its Israeli facility. If Microbot is unsuccessful in hedging against its position in NIS, a change in the value of the NIS compared to the U.S. dollar could increase Microbot's research and development expenses, labor costs and general and administrative expenses, and as a result, have a negative impact on Microbot's profits.

---

***Funding and other benefits provided by Israeli government programs may be terminated or reduced in the future and the terms of such funding may have a significant impact on future corporate decisions.***

Microbot participates in programs under the auspices of the Israeli Office of the Chief Scientist, or OCS, for which it receives funding for the development of its technologies and product candidates. If Microbot fails to comply with the conditions applicable to this program, it may be required to pay additional penalties or make refunds and may be denied future benefits. From time to time, the government of Israel has discussed reducing or eliminating the benefits available under this program, and therefore these benefits may not be available in the future at their current levels or at all.

Microbot's research and development efforts from inception until now have been financed in part through such OCS royalty bearing grants in an aggregate amount of US\$893,673 through September 30, 2016. With respect to such grants Microbot is committed to pay royalties at a rate of between 3% to 3.5% on sales proceeds up to the total amount of grants received, linked to the dollar, plus interest at an annual rate of USD LIBOR. In addition, as a recipient of OCS grants, Microbot must comply with the requirements of the Israeli Encouragement of Industrial Research and Development Law, 1984, or the R&D Law, and related regulations. Under the terms of the grants and the R&D Law, Microbot is restricted from transferring any technologies, know-how, manufacturing or manufacturing rights developed using OCS grants outside of Israel without the prior approval of OCS. Therefore, if aspects of its technologies are deemed to have been developed with OCS funding, the discretionary approval of an OCS committee would be required for any transfer to third parties outside of Israel of the technologies, know-how, manufacturing or manufacturing rights related to such aspects. Furthermore, the OCS may impose certain conditions on any arrangement under which it permits Microbot to transfer technology or development outside of Israel or may not grant such approvals at all.

If approved, the transfer of OCS-supported technology or know-how outside of Israel may involve the payment of significant fees, which will depend on the value of the transferred technology or know-how, the total amount OCS funding received by Microbot, the number of years since the funding and other factors. These restrictions and requirements for payment may impair Microbot's ability to sell its technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. Furthermore, the amount of consideration available to Microbot's shareholders in a transaction involving the transfer of technology or know-how developed with OCS funding outside of Israel (such as through a merger or other similar transaction) may be reduced by any amounts that Microbot is required to pay to the OCS.

***Some of Microbot's employees and officers are obligated to perform military reserve duty in Israel.***

Generally, Israeli adult male citizens and permanent residents are obligated to perform annual military reserve duty up to a specified age. They also may be called to active duty at any time under emergency circumstances, which could have a disruptive impact on Microbot's workforce.

***It may be difficult to enforce a non-Israeli judgment against Microbot or its officers and directors.***

The operating subsidiary of the Company is incorporated in Israel. Some of Microbot's executive officers and directors are not residents of the United States, and a substantial portion of Microbot's assets and the assets of its executive officers and directors are located outside the United States. Therefore, a judgment obtained against Microbot, or any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not necessarily be enforced by an Israeli court. It also may be difficult to affect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Additionally, it may be difficult for an investor, or any other person or entity, to initiate an action with respect to U.S. securities laws in Israel. Israeli courts may refuse to hear a claim based on an alleged



violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law often involves the testimony of expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against Microbot in Israel, it may be impossible to collect any damages awarded by either a U.S. or foreign court.

### **Risks Relating to Microbot's Securities and Governance Matters**

*Our executive officers and directors, through their ownership of common stock, can substantially influence the outcome of matters requiring shareholder approval and may prevent you and other stockholders from influencing significant corporate decisions, which could result in conflicts of interest that could cause the Company's stock price to decline.*

Our executive officers and directors collectively beneficially own shares of Common Stock equal to approximately 41% of our outstanding shares of Common Stock. As a result, such individuals will have the ability, acting together, to substantially influence the election of our directors and the outcome of corporate actions requiring shareholder approval, such as: (i) a merger or a sale of our Company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our articles of incorporation and bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other shareholders and be disadvantageous to our shareholders with interests different from those individuals. These individuals also have significant control over our business, policies and affairs as officers and/or directors of our Company. These stockholders may exert influence in delaying or preventing a change in control of the Company, even if such change in control would benefit the other stockholders of the Company. Lastly, the significant concentration of stock ownership may adversely affect the market value of the Company's common stock due to investors' perception that conflicts of interest may exist or arise. Therefore, you should not invest in reliance on your ability to have any control over the Company.

*We do not expect to pay cash dividends on our common stock.*

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends on our Common Stock in the future. Investors seeking cash dividends should not invest in our Common Stock for that purpose.

*Anti-takeover provisions in the Company's charter and bylaws under Delaware law may prevent or frustrate attempts by stockholders to change the board of directors or current management and could make a third-party acquisition of the Company difficult.*

Provisions in the Company's certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors. In addition, because the Company is incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding Company voting stock from merging or combining with the Company. Although the Company believes these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with the Company's board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by the Company's stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing members of management.





***The market price for our Common Stock may be volatile.***

The market price for our Common Stock may be volatile and subject to wide fluctuations in response to factors including the following:

actual or anticipated fluctuations in our quarterly or annual operating results;

changes in financial or operational estimates or projections;

conditions in markets generally;

changes in the economic performance or market valuations of companies similar to ours;

announcements by us or our competitors of new products, acquisitions, strategic partnerships, joint ventures or capital commitments;

our intellectual property position; and

general economic or political conditions in the United States, Israel or elsewhere.

In addition, the securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our Common Stock.

***The issuance of shares upon exercise of outstanding warrants could cause immediate and substantial dilution to existing stockholders.***

The issuance of shares upon exercise of warrants could result in substantial dilution to the interests of other stockholders since the holders of such warrants may ultimately convert and sell the full amount issuable on conversion.

**Risks Relating to the Merger**

***The total number of shares issued by us as consideration to the former securityholders of Microbot Israel, and the resulting dilution that our current stockholders experienced because of it, was significant.***

The former stockholders of Microbot Israel received as consideration for the Merger, in the aggregate, 26,644,979 shares of our common stock. The shares now held by the former stockholders of Microbot Israel represent a majority of the company, resulting in significant dilution to our pre-Merger stockholders. As of the closing of the Merger, the former stockholders of Microbot represent 75% of our total outstanding shares of Common Stock on a fully-diluted, as converted basis.



***Because our determination to purchase Microbot Israel was based in part on certain financial and other projections about future results, and projections are subject to inherent risks and uncertainties, the Merger consideration may be greater than the fair market value of Microbot Israel.***

Microbot Israel provided financial and other projections to us in connection with the determination to purchase Microbot Israel and the consideration to be paid for Microbot Israel, and we relied in part on Microbot Israel's projections for purposes of valuing Microbot Israel and agreeing on the purchase price. The valuation was not necessarily indicative of the actual value of Microbot Israel. Accordingly, if actual financial results in the future are lower than the projections we relied upon, the consideration may be greater than the fair market value of Microbot Israel, as acquired.

We can give no assurance that the financial and other projections we relied upon are accurate and will be met in the future because the projections reflect numerous estimates and assumptions with respect to industry performance, general business, economic, regulatory, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond Microbot Israel's and our control. As a result, actual results may differ materially from these projections. It is expected that there will be differences between actual and projected results because the projections covered multiple years and such information by its nature becomes less reliable with each successive year.

***If the benefits of the acquisition of Microbot Israel do not meet the expectations of the marketplace, or financial or industry analysts, the market price of our common stock may decline.***

The market price of our common stock may decline as a result of the Merger if the Microbot Israel subsidiary does not perform as expected or we do not otherwise achieve the perceived benefits of the Merger as rapidly as, or to the extent anticipated by the marketplace or financial or industry analysts. Accordingly, investors may experience a loss as a result of a decreasing stock price and we may not be able to raise future capital, if necessary, in the equity markets.

***Any weakness in internal control over financial reporting or disclosure controls and procedures could result in a loss of investor confidence in our financial reports and lead to a stock price decline.***

We are required to evaluate our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 and report the results in our annual report on Form 10-K. We are also required to maintain effective disclosure controls and procedures. After the acquisition of Microbot Israel, our internal controls and our disclosure controls and procedures will need to expand to encompass activities related to those assets. If material weakness arise as a result and they are not remedied, we will be unable to assert that our internal controls are effective. Any failure to have effective internal control over financial reporting or disclosure controls and procedures covering the combined business post-Merger could cause investors to lose confidence in the accuracy and completeness of our financial reports, limit our ability to raise financing or lead to regulatory sanctions, any of which could result in a material adverse effect on our business or decline in the market price of our common stock.

**IN ADDITION TO THE ABOVE RISKS, BUSINESSES ARE OFTEN SUBJECT TO RISKS NOT FORESEEN OR FULLY APPRECIATED BY MANAGEMENT. IN REVIEWING THIS CURRENT REPORT ON FORM 8-K, POTENTIAL INVESTORS SHOULD KEEP IN MIND THAT THERE MAY BE OTHER POSSIBLE RISKS THAT COULD BE IMPORTANT.**

## **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations ( MD&A ) covers information pertaining to the Company up to September 30, 2016 and should be read in conjunction with the audited financial statements and related notes of the Company as of and for the year ended December 31, 2015 and 2014, as well as the unaudited financial statements and related notes of the Company for the three and nine month periods ended September 30, 2016. Except as otherwise noted, the financial information contained in this MD&A and in the financial statements has been prepared in accordance with accounting principles generally accepted in the United States of America. All amounts are expressed in U.S. dollars unless otherwise noted.*

### **Forward Looking Statements**

Certain information contained in this MD&A includes forward-looking statements. Statements which are not historical reflect our current expectations and projections about our future results, performance, liquidity, financial condition and results of operations, prospects and opportunities and are based upon information currently available to us and our management and their interpretation of what is believed to be significant factors affecting our existing and proposed business, including many assumptions regarding future events. Actual results, performance, liquidity, financial condition and results of operations, prospects and opportunities could differ materially and perhaps substantially from those expressed in, or implied by, these forward-looking statements as a result of various risks, uncertainties and other factors, including those risks described in detail in the section of this Current Report on Form 8-K entitled Risk Factors as well as elsewhere in this Current Report.

Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words may, should, would, will, could, scheduled, expect, anticipate, believe, intend, seek, or project or the negative of these words or other variations on these words or comparable terminology.

In light of these risks and uncertainties, and especially given the nature of our existing and proposed business, there can be no assurance that the forward-looking statements contained in this section and elsewhere in this Current Report on Form 8-K will in fact occur. Potential investors should not place undue reliance on any forward-looking statements. Except as expressly required by the federal securities laws, there is no undertaking to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances or any other reason.

### **Overview**

Microbot is a pre-clinical medical device company specializing in the research, design and development of next generation micro-robotics assisted medical technologies targeting the minimally invasive surgery space. Microbot is primarily focused on leveraging its micro-robotic technologies with the goal of improving surgical outcomes for patients.



Microbot is currently developing its first two product candidates: the Self Cleaning Shunt, or SCS, for the treatment of hydrocephalus and Normal Pressure Hydrocephalus, or NPH; and TipCAT, a self-propelling, semi-disposable endoscope that is being developed initially for use in colonoscopy procedures. Microbot's product candidates are being designed to bring greater functionality to conventional medical devices and to reduce the known risks associated with such devices. Microbot is currently aiming to complete pre-clinical or clinical data collection for both product candidates within the next 24 months and is targeting approval or clearance for SCS by late 2018.

Microbot has no products approved for commercial sale and has not generated any revenues from product sales since its inception in 2010. From inception to September 30, 2016, Microbot has raised net cash proceeds of approximately \$5,377,631 to fund operations, primarily from government grants, loans, and private placement offerings of debt and equity securities.

Microbot has never been profitable and has incurred significant operating losses in each year since inception. Net losses for the nine months ended September 30, 2016 and 2015 were approximately \$1,963,340 and \$521,664, respectively, and net losses for the year ended December 31, 2015 were approximately \$920,840. Substantially all of Microbot's operating losses resulted from expenses incurred in connection with its research and development programs and from general and administrative costs associated with its operations. As of September 30, 2016, Microbot had a net working capital of approximately \$201,763, consisting primarily of cash and cash equivalents. Microbot expects to continue to incur significant expenses and increasing operating losses for at least the next several years as it continues the clinical development of, and seeks regulatory approval for its product candidates. Accordingly, Microbot will continue to require substantial additional capital to continue its clinical development and potential commercialization activities. The amount and timing of Microbot's future funding requirements will depend on many factors, including the timing and results of its clinical development efforts.

Estimated completion dates and costs for Microbot's clinical development and research programs can vary significantly for each current and future product candidate and are difficult to predict. As a result, Microbot cannot estimate with any degree of certainty the costs it will incur in connection with development of its product candidates at this point in time. Microbot anticipates it will make determinations as to which programs and product candidates to pursue and how much funding to direct to each program and product candidate on an ongoing basis in response to the scientific success of early research programs, results of ongoing and future clinical trials, its ability to enter into collaborative agreements with respect to programs or potential product candidates, as well as ongoing assessments as to each current or future product candidate's commercial potential.

### **Recent Developments**

On November 28, 2016, Merger Sub, a wholly-owned subsidiary of the Company, completed its merger with and into Microbot Israel, with Microbot Israel surviving as a wholly-owned subsidiary of the Company. On November 28, 2016, in connection with the Merger, the Company changed its name from StemCells, Inc. to Microbot Medical Inc.

Following the closing of the Merger, former StemCells stockholders owned approximately 5% of the Company, with the remaining approximately 95% of the Company ownership comprised approximately 75% of Microbot Israel shareholders and approximately 20% by certain advisors (which includes an existing Microbot Israel shareholder).

In connection with the Merger, Microbot Israel is deemed to be the accounting acquirer because the shareholders of Microbot Israel effectively control the Company following the Merger. The Merger was treated as a reverse acquisition.

On November 29, 2016, we sold certain stem and progenitor lines that have been researched, studied or manufactured by StemCells since 2007, and certain other tangible and intangible assets, including intellectual property and books and records related to the foregoing, in exchange for \$4 million. Of the consideration, \$300,000 was paid prior to November 11, 2016, \$400,000 is being held in escrow to satisfy any indemnification claims of buyer, and \$495,000 was paid to certain StemCells employees, leaving an aggregate of approximately \$2.8 million released to the Company at closing.

As of December 27, 2017, the Company issued 9,736 shares of a newly-designated Series A Convertible Preferred Stock, in exchange for the cancellation of an aggregate of 9,735,925 shares or rights to acquire shares of Common Stock. Upon the exchange, all such shares of Common Stock were cancelled.

## **Financial Operations Overview**

### ***Research and Development Expenses***

Research and development expenses consist primarily of salaries and related expenses and overhead for Microbot's research, development and engineering personnel, prototype materials and research studies, obtaining and maintaining Microbot's patent portfolio. Microbot expenses its research and development costs as incurred.

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of the costs associated with management costs, professional fees for accounting, auditing, consulting and legal services, and allocated overhead expenses.

Microbot expects that its general and administrative expenses may increase in the future as it expands its operating activities, maintains and expands its patent portfolio and incurs additional costs associated with the Merger, the preparation of becoming a public company and maintaining compliance with exchange listing and SEC requirements. Microbot expects these potential increases will likely include management costs, legal fees, accounting fees, directors and officers' liability insurance premiums and expenses associated with investor relations.

### ***Income Taxes***

Microbot has incurred net losses and has not recorded any income tax benefits for the losses. It is still in its development stage and has not yet generated revenues, therefore, it is more likely than not that sufficient taxable income will not be available for the tax losses to be utilized in the future.

## **Critical Accounting Policies and Significant Judgments and Estimates**

Microbot's management's discussion and analysis of its financial condition and results of operations are based on its financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires Microbot to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities at the date of the financial statements. On an ongoing basis, Microbot evaluates its estimates and judgments, including those related to accrued research and development expenses. Microbot bases its estimates on historical experience, known



trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

While Microbot's significant accounting policies are described in more detail in the notes to its financial statements, Microbot believes the following accounting policies are the most critical for fully understanding and evaluating its financial condition and results of operations.

**Foreign Currency Translation**

Microbot's functional currency is the U.S. dollars, and its reporting currency is the U.S. dollar.

**Government Grant and Input Tax Credit Recoveries**

Microbot from time to time has received, and may in the future continue to receive, grants from the Israeli Office of the Chief Scientist to cover eligible company expenditures. These are presented as other income in the statement of operations and comprehensive loss as the grant funds are used for or applied towards a number of Microbot's operating expenses, such as salaries and benefits, research and development and professional and consulting fees. The recoveries are recognized in the corresponding period when such expenses are incurred.

**Research and Development Expenses**

Microbot recognizes research and development expenses as incurred, typically estimated based on an evaluation of the progress to completion of specific tasks using data such as clinical site activations, manufacturing steps completed, or information provided by vendors on their actual costs incurred. Microbot determines the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. These estimates are made as of each balance sheet date based on facts and circumstances known to Microbot at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, Microbot will adjust the estimate accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are capitalized as prepaid expenses and recognized as expense in the period that the related goods are consumed or services are performed.

Microbot may pay fees to third-parties for manufacturing and other services that are based on contractual milestones that may result in uneven payment flows. There may be instances in which payments made to vendors will exceed the level of services provided and result in a prepayment of the research and development expense.

**Results of Operations****Comparison of Nine Months Ended September 30, 2016 and 2015**

The following table sets forth the key components of Microbot's results of operations for the nine months ended September 30, 2016 and 2015 (in thousands):

	<b>Nine Months Ended</b>		
	<b>September 30, 2016</b>	<b>2015</b>	<b>Increase/ (Decrease)</b>
Research and Development Expenses	603	478	125
General and Administrative Expenses	1,120	45	1,075
Financing Expenses	241	(1)	242

*Research and Development Expenses.* Microbot's research and development expenses were approximately \$603,000 for the nine months ended September 30, 2016, compared to approximately \$478,000 for the same period in 2015. The increase in research and development expenses of



approximately \$125,000 in 2016 was primarily due to decrease in cash received from the CSO participation. Microbot expects its research and development expenses to increase over time as Microbot advances its development programs and begins pre-clinical and clinical trials for SCS and TipCAT.

*General and Administrative Expenses.* General and administrative expenses were approximately \$1,120,000 for the nine months ended September 30, 2016, compared to approximately \$45,000 for the same period in 2015. The increase in general and administrative expenses of approximately \$1,075,000 in 2016 was primarily due to Share based compensation as of \$675,000 and legal and professional services paid mainly due to the merger activities. Microbot believes its general and administrative expenses may increase over time as it advances its programs, increases its headcount and operating activities and incurs expenses associated with being a public company.

*Financing Expenses.* Financing expenses were approximately \$241,000 for the nine months ended September 30, 2016, compared to income of approximately \$1,000 for the same period in 2015. The increase in financial expenses was primarily due to revaluation and interest of Microbot's convertible loans and currency exchange differences.

### ***Comparison of the Years Ended December 31, 2015 and 2014***

The following table sets forth the key components of Microbot's results of operations for the years ended December 31, 2015, 2014 (in thousands):

	<b>2015</b>	<b>2014</b>	<b>Change in 2015 Versus 2014</b>
Research and Development Expenses	823	837	(1.67)%
General and Administrative Expenses	92	251	(63)%
Financing Expenses	6	119	(95)%

*Research and Development Expenses.* Research and development expenses, net for the fiscal year ended December 31, 2015 was \$822,759, compared to \$836,698 for the fiscal year ended December 31, 2014, a decrease of approximately \$14,000 or 1.67%. This decrease was primarily attributable to a decrease in expenses relating to the submission of new and maintenance of existing patents and professional services. A portion of Microbot's research and development expenses are paid for through grants received from time to time from the Office of Chief Scientist of the State of Israel. For the fiscal year ended December 31, 2015, Microbot received grants totaling \$201,388, compared to grants totaling \$429,633 for the fiscal year ended December 31, 2014.

Research and development expenses by major programs or categories were as follows (in thousands):

	<b>2015</b>	<b>2014</b>	<b>Change in 2015 Versus 2014</b>
Wages and related expenses	465	480	(3.1)%
Professional services	365	537	(32.0)%
Patents	37	116	(68.1)%
Other	158	134	(17.9)%
	\$ 1,025	\$ 1,267	(19.1)%
Less grants received from Chief Scientist	(201)	(429)	(53.1)%

<b>Total</b>	824	838
--------------	-----	-----

*General and Administrative Expenses.* General and administrative expenses for the fiscal year ended December 31, 2015 was \$92,018, compared to \$251,000 for the fiscal year ended December 31, 2014, a decrease of approximately \$158,982, or 63%. This decrease was primarily attributable to a decrease in share-based compensation.

*Financing Expenses.* Financing expenses, net for the fiscal year ended December 31, 2015 was approximately \$6,000, compared to approximately \$119,000 for the fiscal year ended December 31, 2014. Interest expense consists primarily of bank fees and interest, and currency exchange differences. The decrease in interest expense in 2015 over 2014 was due to primarily to currency exchange differences, as well as to a lesser extent on accumulated interest on outstanding convertible loans.

## **Liquidity and Capital Resources**

Microbot has incurred losses since inception and negative cash flows from operating activities for the nine months ended September 30, 2016 and 2015 and for the years ended December 31, 2015 and 2014. As of September 30, 2016, Microbot had a net working capital of approximately \$201,763, consisting primarily of cash and cash equivalents. Microbot anticipates that it will continue to incur net losses for the foreseeable future as it continues research and development efforts of its product candidates, hires additional staff, including clinical, scientific, operational, financial and management personnel, and incurs additional costs associated with being a public company.

Microbot has funded its operations through the issuance of capital stock, grants from the Israeli Office of the Chief Scientist, and convertible debt. As of September 30, 2016, Microbot had raised total net cash of \$5,377,631, which was comprised of \$3,121,958 upon the issuance of capital shares, a \$200,000 strategic investment loan from Johnson & Johnson (non-equity and non-dilutive), approximately \$1,162,000 upon the sale of convertible promissory notes in 2015 and 2016, and three grants from the Israeli Office of the Chief Scientist totaling \$893,673. As of September 30, 2016, Microbot had a shareholders' deficit of \$745,555 and has incurred a total cumulative loss of \$5,149,552 from inception (November 2010) to September 30, 2016 (which reflects a net cumulative loss of \$4,255,879, after a deduction of the Chief Scientist grants which totaled \$893,673).

As a result of the sale of certain of the assets of StemCells, on November 29, 2016, Microbot raised approximately \$2.8 million in cash, after taking into account the payment of \$495,000 to certain StemCells employees but excluding \$400,000 held in escrow to satisfy any indemnification claims of the buyer of the assets. Additionally, a stockholder of Microbot has committed to invest an amount so that, with the funds from the asset sale, Microbot receives an aggregate of \$4 million under certain circumstances, which commitment has not been consummated as of the date of this Form 8-K. As a result of such cash and cash commitments, Microbot believes that its net cash will be sufficient to fund the Company for at least 18 months and fund operations necessary to continue development activities of the SCS and TipCAT.

Microbot's independent registered public accounting firm included an explanatory paragraph in its report on Microbot's financial statements as of and for the year ended December 31, 2015, describing the continuation of Microbot's activities and its ability to fulfill its obligations as dependent upon its ability to receive financing from its shareholders or new investors.

Microbot plans to continue to fund its research and development and other operating expenses, other development activities relating to additional product candidates, and the associated losses from operations, through future issuances of debt and/or equity securities and possibly additional grants from the Israeli Office of the Chief Scientist. The capital raises from issuances of convertible debt and equity securities could result in additional dilution to Microbot's shareholders. In addition, to the extent Microbot determines to incur additional indebtedness, Microbot's incurrence of additional debt could result in debt service obligations and operating and financing covenants that would restrict its operations. Microbot can provide no assurance that financing will be available in the amounts it needs or on terms acceptable to it, if at all. If Microbot is not able to secure adequate additional working capital when it becomes

needed, Microbot may be required to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned research programs. Any of these actions could materially harm Microbot's business.

**Cash Flows**

The following table provides a summary of the net cash flow activity for each of the periods set forth below (in thousands):

	<b>Nine Month Ended September 30,</b>		<b>Year Ended December 31,</b>
	<b>2016</b>	<b>2015</b>	<b>2015</b>
Net cash used in operating activities	\$ (767)	\$ (493)	\$ (765)
Net cash provided by financing activities	904		412
Net increase (decrease) in cash and cash equivalents	137	(495)	(354)

**Comparison of the Nine Months Ended September 30, 2016 and 2015**

Cash used in operating activities for the nine months ended September 30, 2016 was approximately \$767,000, calculated by adjusting net loss from operations by approximately \$1,196,000 to eliminate non-cash and expense items not involving cash flows such as depreciation and accumulated interest on convertible loans, as well as other changes in assets and liabilities resulting in non-cash adjustments in the income statement. Cash used in operating activities for the nine months ended September 30, 2015 was approximately \$493,000, similarly adjusted by approximately \$28,000. Net cash provided by financing activities of \$904,000 for the nine months ended September 30, 2016 consisted of proceeds from the sale of convertible promissory notes to existing shareholders of Microbot, compared to \$nil in the nine months ended September 30, 2015.

**Comparison of the Years Ended December 31, 2015 and 2014**

Cash used in operating activities for the year ended December 31, 2015 was approximately \$764,000, calculated by adjusting net loss from operations by approximately \$156,000 to eliminate non-cash and expense items not involving cash flows such as depreciation and accumulated interest on convertible loans, as well as other changes in assets and liabilities resulting in non-cash adjustments in the income statement. Cash used in operating activities for the year ended December 31, 2014 was approximately \$1,063,000, similarly adjusted by approximately \$144,000. Net cash provided by financing activities of \$412,494 for the year ended December 31, 2015 consisted of proceeds from the sale of convertible promissory notes to existing shareholders of Microbot. Net cash provided by financing activities of approximately \$1,503,000 for the year ended December 31, 2014 consisted of net proceeds from the exercise of outstanding warrants for shares of the Series A Preferred Stock of Microbot.

**Off Balance Sheet Arrangements**

Microbot has no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

**Quantitative and Qualitative Disclosures about the Market Risk of Microbot****Interest Rate Risk**

Microbot's cash and cash equivalents as of September 30, 2016 consisted of readily available checking and money market funds. Microbot's primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in Microbot's



portfolio, a sudden change in market interest rates would not be expected to have a material impact on Microbot's financial condition and/or results of operations. Microbot does not believe that its cash or cash equivalents have significant risk of default or illiquidity. While Microbot believes its cash and cash equivalents do not contain excessive risk, Microbot cannot provide absolute assurance that in the future its investments will not be subject to adverse changes in market value. In addition, Microbot maintains significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

### *Effects of Inflation*

Inflation generally affects Microbot by increasing its clinical trial costs. Microbot does not believe that inflation and changing prices had a significant impact on its results of operations for any periods presented herein.

## **DESCRIPTION OF SECURITIES**

### **General**

Our authorized capital stock consists of 221,000,000 shares of capital stock, which consists of 220,000,000 shares of common stock, par value \$0.01 (the **Common Stock** ), and 1,000,000 of undesignated preferred stock, par value \$0.01 (the **Preferred Stock** ). As of January 3, 2017, we had approximately 26,551,000 shares of Common Stock issued and outstanding, and 9,736 shares of Series A Convertible Preferred Stock issued and outstanding.

### **Common Stock**

Holders of Common Stock are entitled to one vote per share on matters on which our stockholders vote. There are no cumulative voting rights. Holders of Common Stock are entitled to receive dividends, if declared by our board of directors, out of funds that we may legally use to pay dividends. If we liquidate or dissolve, holders of Common Stock are entitled to share ratably in our assets once our debts and any liquidation preference owed to any then-outstanding preferred stockholders are paid. Our certificate of incorporation does not provide the Common Stock with any redemption, conversion or preemptive rights.

### **Preferred Stock**

The Company is currently authorized to issue up to 1,000,000 shares of Preferred Stock, \$0.01 par value per share, of which 9,736 shares have currently been designated as Series A Convertible Preferred Stock (the **Series A Stock** ) and are issued and outstanding. The Board of Directors is authorized to fix the dividend rights, dividend rate, voting rights, conversion rights, rights and terms of redemption and liquidation preferences of any wholly unissued series of preferred stock and the number of shares constituting any series and the designation thereof, of any of them.

Each share of Series A Stock shall be convertible, at any time and from time to time from and after the original issue date at the option of the holder thereof, into 1,000 shares of Common Stock, subject to customary adjustments for stock dividends, stock splits and other fundamental transactions, and are further subject to a beneficial ownership limitation of 4.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of Common Stock issuable upon conversion of the Series A Stock. The Series A Stock have no voting rights, except as may be required by law or for limited purposes specified in the Certificate of Designation with respect to the Series A Stock.

## MANAGEMENT OF THE COMPANY

### Executive Officers and Directors

The Company's board of directors currently consists of six (6) members, consisting of Harel Gadot, Yoav Waizer, Moshe Shoham, Yoseph Bornstein, Solomon Mayer, and Scott Burell. Messrs. Gadot and Waizer are Class I directors whose terms expire at the Company's 2019 annual meeting of stockholders. Messrs. Mayer and Burell are Class II directors whose terms expire at the Company's 2017 annual meeting of stockholders. Messrs. Bornstein and Shoham are Class III directors whose terms expire at the Company's 2018 annual meeting of stockholders.

The following table lists the names, ages and positions of the individuals who serve as executive officers and directors of the Company, as of January 3, 2017:

Name	Age	Position(s)
<i>Executive Officers</i>		
Harel Gadot	44	President, Chief Executive Officer and Chairman of the Board of Directors
David Ben Naim	46	Chief Financial Officer
Yehezkel (Hezi) Himelfarb	59	General Manager and Chief Operating Officer
<i>Non-Employee Directors</i>		
Yoav Waizer	51	Director
Moshe Shoham	65	Director
Yoseph Bornstein	58	Director
Solomon Mayer	63	Director
Scott Burell	51	Director
<i>Executive Officers</i>		

*Harel Gadot*, became President, Chief Executive Officer and Chairman of the Company's Board of Directors following the consummation of the Merger. Mr. Gadot is a co-founder of Microbot Israel and has served as Microbot Israel's Chief Executive Officer since Microbot Israel was founded in November 2010. He has been the Chairman of Microbot Israel's board of directors since July 2014. He also serves as the Chairman of XACT Robotics Ltd. since August 2013 and MEDX Xelerator LP since July 2016. From December 2007 to April 2010 Mr. Gadot was a Worldwide Group Marketing Director at Ethicon Inc., a Johnson and Johnson Company, where he was responsible for the global strategic marketing of the company. Mr. Gadot also held management positions, as well as leading regional strategic position for Europe, Middle-East and Africa, as well as In Israel, while at Johnson and Johnson. Mr. Gadot served as director for ConTIPI Ltd. from August 2010 until November 2013 when ConTIPI Ltd. was acquired by Kimberly-Clark Corporation. Mr. Gadot holds a B.Sc. in Business from Siena College, Loudonville NY, and an M.B.A. from the University of Manchester, UK.

*David Ben Naim*, age 46, became the Company's Chief Financial Officer following the consummation of the Merger. Mr. Ben Naim is the general manager of DBN Finance Services Ltd., a company which provides outsourcing financial services to public and private companies, since 2014. Through DBN Finance Services, Mr. Ben Naim has acted as the outsourced CFO for Emerald Medical Applications Corp. (OTC:MRLA), a digital health startup company engaged in the development, sale and service of imaging solutions, and Tempramed Inc., a private medical device company. Prior to that, Mr. Ben Naim served as Chief Financial Officer for several companies in the



biomedical and technology industries. From July 2012 to September 2014, Mr. Ben Naim served as Chief Financial Officer for Insuline Medical Ltd. (TASE: INSL), an Israel-based company focused on improving performance of insulin treatment methods. From 2008 until 2011, Mr. Ben Naim served as Chief Financial Officer of Crow Technologies 1977 Ltd. (OTC:CRWTF), a company that designs, develops, manufactures and sells a broad range of security and alarm systems. From 2007 to 2008, Mr. Ben Naim served as Chief Financial Officer of Ilex Medical Ltd. (TASE:ILX), a leading company in the medical diagnostics field. From 2003 to 2007, Mr. Ben Naim was the Corporate Controller of Tadiran Telecom Ltd. He started his career in 1998 at Deloitte & Touche where he left in 2003 as an Audit Senior Manager. Mr. Ben Naim holds a B.A. in social sciences from Open University, Israel, a CPA license from Ramat Gan College, Israel, and an M.B.A. from Ono Academic College, Israel.

*Yehezkel (Hezi) Himelfarb*, age 59, became the Company's Chief Operating Officer and General Manager of the Company's Israeli operations on December 5, 2016. Mr. Himelfarb was the Chief Executive Officer from 2008 through November 2016 and a member of the board of directors from 2008 through August 2016 of IceCure Medical Ltd., a Tel Aviv Stock Exchange listed company that develops advanced cryotherapy systems (cryoablation) intended for the growing physician-office market. Prior to that, from 1999 to 2008, Mr. Himelfarb was the President, Chief Executive Officer and a member of the board of directors of Remon Medical Technologies, Inc., a venture backed US/Israeli company that developed and commercialized smart, miniature implants which enabled physicians to assess and treat a variety of medical conditions, where he, among other things, led its acquisition by Boston Scientific. From 1996 to 1999, he was the Vice President and Chief Operating Officer of Medtronic-InStent (Israel), which was part of Medtronic's vascular division. From 1982 to 1996, Mr. Himelfarb had various positions at Scitex Corporation Ltd., which was an Israeli-based company specializing in specialty equipment production. Mr. Himelfarb holds a B.Sc. in Electronic Engineering and an M.B.A. in Marketing and Engineering Management, both from Tel Aviv University.

#### *Non-Employee Directors*

*Yoav Waizer*, became a director of the Company following the Merger and has served as a member of the Board of Directors of Microbot Israel since May 2015. Mr. Waizer is a Partner and Chief Executive Officer of Medica Venture Partners, a healthcare dedicated venture investing out of Israel in innovative capital-starved early stage and special situation companies, since November 2005. Prior to his Tenure at Medica, Mr. Waizer served as CFO & COO at Cedar Fund, a venture capital fund focuses on investing in Israel-related high-tech companies in the telecom, networking, Internet-infrastructure and enterprise software areas and prior to that Mr. Waizer was the CFO of Star Ventures Israel, the Israeli fund of Star Ventures, a \$1 billion venture capital fund investing in all stages of development within the Telecom, Enterprise S/W, Wireless and Life Sciences sectors. Mr. Waizer is currently a director of InterCure Ltd., a company focused on investing in medical technology companies that is traded on the Tel Aviv Stock exchange. Mr. Waizer holds Master of Business Administration in Information Systems and B.Sc. in Accounting and Statistics, both from the Tel-Aviv University.

*Moshe Shoham, D.Sc.*, became a director of the Company following the Merger. Dr. Shoham is a co-founder of Microbot Israel and has served as Chairman of Microbot Israel's Scientific Advisor Board and as a Director since Microbot Israel was founded in November 2010. Prof. Shoham has been the head of the robotics laboratory at the Technion-Israel Institute of Technology, Department of Mechanical Engineering since October 1990 and has been a professor in the Department of Mechanical Engineering at the Technion-Israel Institute of Technology since October 1989. Prior to that, Dr. Shoham was the director of the robotic laboratory in the Department of Mechanical Engineering at Columbia University from September 1986 to September 1989. Dr. Shoham has served as a foreign member of the National Academy of Engineering in the United States since October 2014. In addition, Dr. Shoham founded Mazor Surgical Technologies Ltd., a publically traded medical device company in the field of surgical robotics, and has been its Chief Technology Officer since January 2003. Dr. Shoham earned a B.Sc. in 1978, a M.Sc. in 1982 and a D.Sc. in 1986 from the Technion-Israel Institute of Technology.

*Yoseph Bornstein*, became a director of the Company following the Merger . Mr. Bornstein is a co-founder of Microbot Israel and has been a member of the Board of Directors since Microbot Israel was founded in November 2010. Mr. Bornstein founded Shizim Ltd., a life science holding group in October 2000 and has served as its president since then. Mr. Bornstein is the Chairman of GCP Clinical Studies Ltd., a provider of clinical research services and educational programs in Israel since January 2002. He is the Chairman of Biotis Ltd., a service company for the bio-pharmaceutical industry, since June 2000. In addition, he is the Chairman of Dolphin Medical Ltd., a service company for the medical device industry, since April 2012 and the Chairman of ASIS Enterprises B.B.G. Ltd., a business August 2007. In October 1992, Mr. Bornstein founded Pharmateam Ltd., an Israeli company that specialized in representing international pharmaceutical companies which was sold in 2000. Mr. Bornstein is also a founder of a number of other privately held life-science companies. Mr. Bornstein served as the Biotechnology Committee Chairman of the Unites States-Israel Science & Technology Commission (the USISTF ) from September 2002 to February 2005 as well as a consultant for USISTF from September 2002 to February 2005. He is also the founder of ILSI-Israel Life Science Industry Organization and ITTN-Israel Tech Transfer Organization.

*Solomon Mayer*, became a director of the Company following the Merger. Mr. Mayer has served as a member of the Board of Directors of Microbot Israel since June 2014, as the designated director of Alpha Capital. Mr. Mayer has served as the President and Chief Executive Officer of Mooney Aviation Company since June 1999. He also serves as President of Chailife Line, an organization devoted to help restore normalcy to family life and better enable them to withstand the crises and challenges of serious pediatric illness. In addition, Mr. Mayer serves as a Director of the Laniado Hospital, International Medical Search Co. of New York, Blastgard International, Inc. and Ironwood Gold Corp.

*Scott R. Burell*, became a director of the Company following the Merger and has served as a member of the Board of Directors of Microbot Israel since the closing of the Merger on November 28, 2016. He is the Chief Financial Officer, Secretary and Treasurer of CombiMatrix Corporation, a family health-focused clinical molecular diagnostic laboratory specializing in pre-implantation genetic screening, prenatal diagnosis, miscarriage analysis, and pediatric developmental disorders, since November 2006. He successfully led the split-off of CombiMatrix in 2007 from its former parent, has led several successful public and private debt and equity financing transactions as well as CombiMatrix's reorganization in 2010. Prior to this, Mr. Burell had served as CombiMatrix's Vice President of Finance since November 2001 and as its Controller from February 2001 to November 2001. From May 1999 to first joining CombiMatrix in February 2001, Mr. Burell was the Controller for Network Commerce, Inc., a publicly traded technology and information infrastructure company located in Seattle. Prior to this, Mr. Burell spent 9 years with Arthur Andersen's Audit and Business Advisory practice in Seattle. During his tenure in public accounting, Mr. Burell worked with many clients, both public and private, in the high-tech and healthcare markets, and was involved in numerous public offerings, spin-offs, mergers and acquisitions. Mr. Burell obtained his Washington state CPA license in 1992 and is a certified public accountant (currently inactive). He holds Bachelor of Science degrees in Accounting and Business Finance from Central Washington University.

## **Committees of the Board of Directors**

### ***Audit Committee***

The Audit Committee acts pursuant to a written charter. The primary function of the Audit Committee is to assist the Board of Directors in fulfilling its oversight responsibilities. The Audit Committee does this primarily by reviewing the Company's financial reports and other financial information as well as the Company's systems of internal controls regarding finance, accounting, legal compliance, and ethics that management and the Board of Directors have established. The Audit Committee also assesses the Company's auditing, accounting and financial processes more generally. The Audit Committee recommends to the Board of Directors the appointment of a firm of independent auditors to audit the financial statements of the Company and meets with such personnel of the Company to review the scope and the results of the annual audit, the amount of audit fees, the company's internal accounting controls, the Company's financial statements contained in this proxy statement, and other related matters.

In connection with the closing of the Merger, the Company's Board of Directors elected Messrs. Burell, Waizer and Bornstein to serve as members of the Audit Committee, with Mr. Burell being elected as the Audit Committee financial expert.

### ***Compensation Committee***

The Compensation Committee acts pursuant to a written charter. The Compensation Committee makes recommendations to the Board of Directors and management concerning salaries in general, determines executive compensation and approves incentive compensation for employees and consultants.

In connection with the closing of the Merger, the Company's Board of Directors elected Messrs. Burell and Bornstein to serve as members of the Compensation Committee.

*Nominating and Governance Committee*

The Nominating and Governance Committee acts pursuant to a written charter. The Nominating and Governance Committee oversees nominations to the Board of Directors and considers the experience, ability and



character of potential nominees to serve as directors, as well as particular skills or knowledge that may be desirable in light of the Company's position at any time. The Nominating and Governance Committee also develops and recommends to the Board of Directors a set of corporate governance principles applicable to the company.

In connection with the closing of the Merger, the Company's Board of Directors elected Messrs. Shoham and Waizer to serve as members of the Nominating and Governance Committee.

***Director Independence***

NASDAQ's listing standards and the Company's Corporate Governance Guidelines require that the Company's Board of Directors consist of a majority of independent directors, as determined under the applicable NASDAQ listing standards.

**PRINCIPAL STOCKHOLDERS OF THE COMPANY**

The following table and the related notes present information on the beneficial ownership of shares of the Company by:

each director of the Company;

each executive officer of the Company; and

each stockholder known by us to beneficially own more than five percent of the Company's common stock on an as-converted basis.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Does not include any warrants, options or other convertible securities of the Company, except that shares of the Company's common stock subject to options, warrants and other convertible securities currently exercisable or which may become exercisable within 60 days of January 3, 2017 are deemed outstanding and beneficially owned by the person holding such options or warrants for purposes of computing the number of shares and percentage beneficially owned by such person, but are not deemed outstanding for purposes of computing the percentage beneficially owned by any other person.

This table is based on information supplied by each prospective director, officer and principal stockholder of the Company. Except as indicated in footnotes to this table, the Company believes that the stockholders named in this table have sole voting and investment power with respect to all shares of Common Stock shown to be beneficially owned by them, based on information provided by such stockholders. Unless otherwise indicated, the address for each prospective director and executive officer of the Company listed is: c/o Microbot Medical Inc., 175 Derby Street, 27/1, Hingham, MA 02043.

<b>Beneficial Owner</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percentage of Common Stock Beneficially Owned</b>
<i>Directors and Executive Officers</i>		
Harel Gadot(1)	3,820,664	13.78%

Edgar Filing: Microbot Medical Inc. - Form 8-K

Yoav Waizer		
Moshe Shoham(2)	2,550,231	9.36%
Yoseph Bornstein(3)	5,305,409	19.98%
Solomon Mayer		
Scott Burell		
David Ben Naim		
Yehezkel (Hezi) Himelfarb		
All current directors and executive officers as a group (8 persons)(4)		41.07%

<b>Beneficial Owner</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percentage of Common Stock Beneficially Owned</b>
<i>Five Percent Stockholders</i>		
LSA - Life Science Accelerator Ltd.(3)	5,305,409	19.98%
Technion Research and Development Foundation	3,555,339	13.39%
MEDX Ventures Group LLC(5)	3,820,664	13.78%
Leon Lewkowicz	3,149,438	11.86%
Saber Holding GmbH	4,307,003	16.22%
GreenBlock Capital	1,950,660	7.35%
Lane Ventures	1,950,660	7.35%

- (1) Includes 1,167,960 shares of the Company's common stock issuable upon the exercise of options granted to MEDX Ventures Group. All of such shares and options are held by MEDX Ventures Group LLC, which is beneficially owned by Mr. Gadot. See Note 5 below.
- (2) Includes 708,141 shares of the Company's common stock issuable upon the exercise of options.
- (3) Based on representations and other information made or provided to Microbot by Mr. Bornstein, Mr. Bornstein is the CEO and Director of LSA and of Shizim, and Mr. Bornstein is the majority equity owner of Shizim. Shizim is the majority equity owner of LSA. Accordingly, Mr. Bornstein may be deemed to share voting and investment power over the shares beneficially owned by these entities.
- (4) Includes shares of the Company's common stock issuable upon the exercise of options as set forth in footnotes (1) and (2).
- (5) Includes 1,167,960 shares of the Company's common stock issuable upon the exercise of options granted to MEDX Ventures Group. Mr. Gadot is the Chief Executive Officer, Company Group Chairman and majority equity owner of MEDX Venture Group and thus may be deemed to share voting and investment power over the shares beneficially owned by this entity.

**Item 9.01 Financial Statements and Exhibits**

<b>Exhibit</b>	<b>Description</b>
23.1	Consent of Brightman Almagor Zohar & Co., a Member of Deloitte Touche Tohmatsu Limited
23.2	Consent of Brightman Almagor Zohar & Co., a Member of Deloitte Touche Tohmatsu Limited
99.1	Audited Financial Statements for the Fiscal Years ended December 31, 2015 and 2014
99.2	Condensed unaudited financial statements for the periods ended September 30, 2016 and 2015
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

\* To be filed by amendment.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: January 4, 2017

**MICROBOT MEDICAL INC.**

By: /s/ Harel Gadot  
Harel Gadot, Chairman, President, and  
Chief Executive Officer